PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 06 October 2000 (06.10.00)	
International application No. PCT/US00/00604	**Applicant's or agent's file reference** 9904PC1/2280
International filing date (day/month/year) 11 January 2000 (11.01.00)	**Priority date** (day/month/year) 11 January 1999 (11.01.99)
Applicant BOYD, Lawrence, M. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

09 August 2000 (09.08.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer F. Baechler
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

US0000604

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 July 2000 (20.07.2000)

PCT

(10) International Publication Number
WO 00/41655 A3

(51) International Patent Classification[7]: A61F 2/44

(21) International Application Number: PCT/US00/00604

(22) International Filing Date: 11 January 2000 (11.01.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/115,388 11 January 1999 (11.01.1999) US

(71) Applicant *(for all designated States except US)*: **SDGI HOLDINGS, INC.** [US/US]; Suite 508, 300 Delaware Avenue, Wilmington, DE 19801 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BOYD, Lawrence, M.** [US/US]; 688 S. McLean Boulevard, Memphis, TN 38104 (US). **BURKUS, J., Kenneth** [US/US]; 7162 Williams Hill Road, Columbus, GA 31904 (US). **DORCHAK, John, D.** [US/US]; P.O. Box 400, Midland, GA 31820 (US).

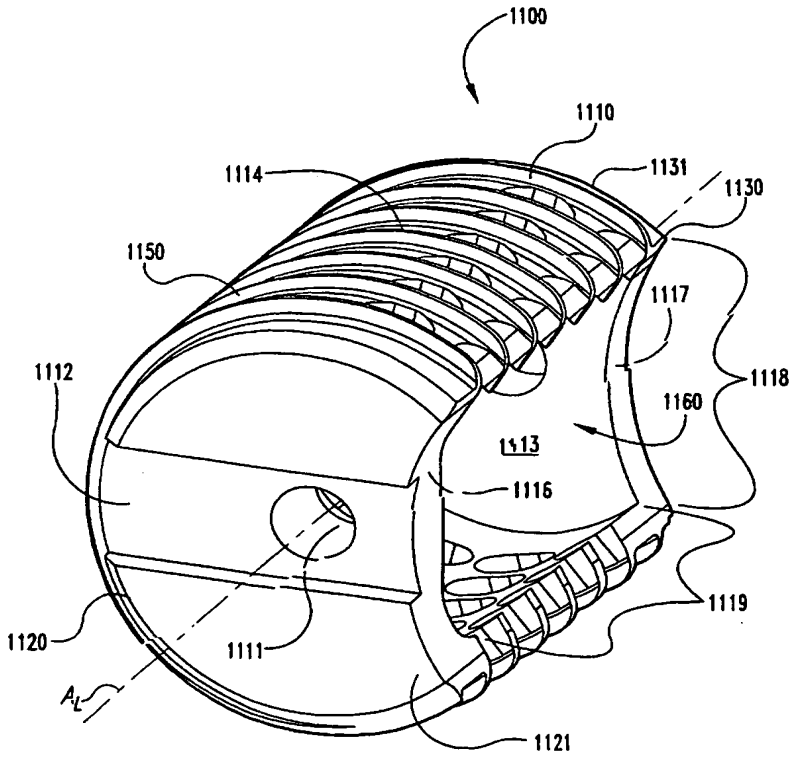
(74) Agents: **GANDY, Kenneth, A.** et al.; Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).

(81) Designated States *(national)*: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent

[Continued on next page]

(54) Title: INTERVERTEBRAL SPACERS WITH SIDE WALL ACCESSIBLE INTERIOR CAVITY



(57) Abstract: Intervertebral spacers, tools for implanting intervertebral spacers and methods of promoting fusion bone growth in the space between adjacent vertebrae are provided. The spacers include an elongated body having a first end, a second end and an outer surface. Side walls connect the first and second ends. The elongated body also defines an interior cavity. The side wall defines an opening to the interior cavity in a side of the elongated body. At least one of the first and second ends has a discontinuity, such as a concave surface, for nesting with an adjacent spacer. The tools include spacer engaging means for engaging a spacer and occlusion means for blocking an opening defined in the spacer. In some embodiments, the occlusion means includes a plate extendible from the housing. In one specific embodiment the plate defines a groove which is disposed around a fastener attached to the housing so that the plate is slideable relative to the housing. The methods of promoting fusion bone growth include utilizing the inventive spacers described herein.

WO 00/41655 A3

(AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *With international search report.*

— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

(88) Date of publication of the international search report:
7 December 2000

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 2/44	A2	(11) International Publication Number: **WO 00/41655** (43) International Publication Date: 20 July 2000 (20.07.00)

(21) International Application Number: PCT/US00/00604

(22) International Filing Date: 11 January 2000 (11.01.00)

(30) Priority Data:
60/115,388 11 January 1999 (11.01.99) US

(71) Applicant *(for all designated States except US)*: SDGI HOLDINGS, INC. [US/US]; Suite 508, 300 Delaware Avenue, Wilmington, DE 19801 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: BOYD, Lawrence, M. [US/US]; 688 S. McLean Boulevard, Memphis, TN 38104 (US). BURKUS, J., Kenneth [US/US]; 7162 Williams Hill Road, Columbus, GA 31904 (US). DORCHAK, John, D. [US/US]; P.O. Box 400, Midland, GA 31820 (US).

(74) Agents: GANDY, Kenneth, A. et al.; Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).

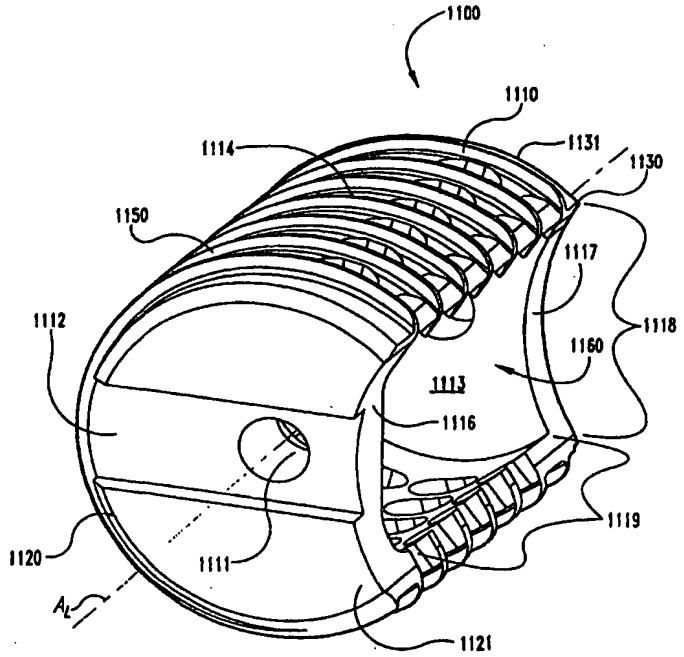
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: INTERVERTEBRAL SPACERS WITH SIDE WALL ACCESSIBLE INTERIOR CAVITY

(57) Abstract

Intervertebral spacers, tools for implanting intervertebral spacers and methods of promoting fusion bone growth in the space between adjacent vertebrae are provided. The spacers include an elongated body having a first end, a second end and an outer surface. Side walls connect the first and second ends. The elongated body also defines an interior cavity. The side wall defines an opening to the interior cavity in a side of the elongated body. At least one of the first and second ends has a discontinuity, such as a concave surface, for nesting with an adjacent spacer. The tools include spacer engaging means for engaging a spacer and occlusion means for blocking an opening defined in the spacer. In some embodiments, the occlusion means includes a plate extendible from the housing. In one specific embodiment the plate defines a groove which is disposed around a fastener attached to the housing so that the plate is slideable relative to the housing. The methods of promoting fusion bone growth include utilizing the inventive spacers described herein.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

INTERVERTEBRAL SPACERS WITH SIDE WALL ACCESSIBLE INTERIOR CAVITY

The present application claims the benefit of U.S. Provisional Patent Application Serial Number 60/115,388, filed on January 11, 1999, which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

The present invention broadly concerns arthrodesis for stabilizing the spine. More specifically, the invention provides open-chambered intervertebral spacers, instruments for implanting the spacers and methods for promoting fusion bone growth between adjacent vetebrae.

Intervertebral discs, located between the endplates of adjacent vertebrae, stabilize the spine, distribute forces between vertebrae and cushion vertebral bodies. A normal intervertebral disc includes a semi-gelatinous component, the nucleus pulposus, which is surrounded and confined by an outer, fibrous ring called the annulus fibrosus. In a healthy, undamaged spine, the annulus fibrosus prevents the nucleus pulposus from protruding outside the disc space.

Spinal discs may be displaced or damaged due to trauma, disease or aging. Disruption of the annulus fibrosus allows the nucleus pulposus to protrude into the vertebral canal, a condition commonly referred to as a herniated or ruptured disc. The extruded nucleus pulposus may press on a spinal nerve, which may result in nerve damage, pain, numbness, muscle weakness and paralysis. Intervertebral discs may also deteriorate due to the normal aging process or disease. As a disc dehydrates and hardens, the disc space height will be reduced leading to instability of the spine, decreased mobility and pain.

Sometimes the only relief from the symptoms of these conditions is a discectomy, or surgical removal of a portion or all of an intervertebral disc followed by fusion of the adjacent vertebrae. The removal of the damaged or unhealthy disc will allow the disc space to collapse. Collapse of the disc space can cause instability of the spine, abnormal joint mechanics, premature development of arthritis or nerve damage, in addition to severe pain. Pain relief via discectomy and arthrodesis requires preservation of the disc space and eventual fusion of the affected motion segments.

Bone grafts are often used to fill the intervertebral space to prevent disc space collapse and promote fusion of the adjacent vertebrae across the disc space. In early techniques, bone material was simply disposed between the adjacent vertebrae, typically at the posterior aspect of the vertebra, and the spinal column was stabilized by way of a plate or rod spanning the affected vertebrae. Once fusion occurred, the hardware used to maintain the stability of the segment became superfluous and was a permanent foreign body. Moreover, the surgical procedures necessary to implant a rod or plate to stabilize the level during fusion were frequently lengthy and involved.

It was therefore determined that a more optimal solution to the stabilization of an excised disc space is to fuse the vertebrae between their respective end plates, preferably without the need for anterior or posterior plating. There have been an extensive number of attempts to develop an acceptable intradiscal implant that could be used to replace a damaged disc and maintain the stability of the disc interspace between the adjacent vertebrae, at least until complete arthrodesis is achieved. The implant must provide temporary support and allow bone ingrowth. Success of the discectomy and fusion procedure requires the development of a contiguous growth of bone to create a solid mass because the implant may not withstand the compressive loads on the spine for the life of the patient.

Several metal spacers have been developed to fill the void formed and to promote fusion. Sofamor Danek Group, Inc., (1800 Pyramid Place, Memphis, TN 38132, (800) 933-2635) markets a number of hollow spinal cages. For

example, U.S. Patent No. 5,015,247 to Michelson and U.S. Serial No. 08/411,017 to Zdeblick disclose a threaded spinal cage. The cages are hollow and can be filled with osteogenic material, such as autograft or allograft, prior to insertion into the intervertebral space. Apertures defined in the cage communicate with the hollow interior to provide a path for tissue growth between the vertebral endplates. In many cases, in order to provide spacers having sufficient load bearing capacity, two spacers must be bilaterally placed in the intervertebral space. The challenge in bilateral placement is to use properly sized spacers having sufficient load bearing capacity so that they will provide adequate support and will not extend outside of the intervertebral space where they could interfere with other spinal-associated structures, including the various spinal nerves and blood vessels. A need therefore exists for such spacers. The present invention addresses this need.

SUMMARY OF THE INVENTION

This invention provides preferred interbody fusion spacers having features allowing for side-loading of substances into an interior cavity and also preferably allowing them to nest within each other, and thus allowing close placement of one or more spacers within the intervertebral space, tools for implanting the spacers and methods for promoting fusion bone growth between adjacent vertebrae. In one form of the invention, the spacers include an elongated body having a first end, a second end, an outer surface and a side wall connecting the first and second end. The elongated body defines a chamber, or interior cavity, that may optionally be filled with osteogenic materal. At least one of the first and second ends, preferably both, has a discontinuity, such as a concave surface, for nesting with an adjacent spacer. The side walls of the inventive spacers define an opening to the interior cavity in a side of the elongated body, for loading a substance such as an osteogenic or osteoconductive substance, into the interior cavity.

In yet other forms of the invention, the spacers include an elongated body having a circumference, a first end wall, a second end wall, an outer surface and a side wall connecting the first and second end. The body defines a chamber, or interior cavity, and preferably has a plurality of openings for bone ingrowth that extend from the outer surface of elongated body into the interior cavity. In one embodiment, the side walls define a large opening communicating with the internal cavity of the spacer, for example extending from about 10% to about 50% around the circumference of the body, and extending along at least about 50% of the length of the body. The end walls are perferably configured for nesting with an adjacent spacer. Preferably, the discontinuities in the end walls and side walls both extend about the circumference of the body to substantially the same extent.

In other aspects of the invention, interbody fusion implant systems are provided. In one form of the invention, the systems include a first interbody fusion spacer as described above, along with a second interbody fusion spacer

as defined above. The second interbody fusion spacer may or may not have discontinuities in the end and/or side walls similar to those in the first spacer.

Tools for implanting spacers are also provided. The tools include spacer engaging means for engaging a spacer and occlusion means for blocking an opening defined in the spacer. In one form of the invention, the engaging means includes a shaft slidingly disposed within a housing and having a threaded post for engaging a threaded tool hole in the spacer. In some embodiments, the occlusion means includes a plate extendible from the housing. In one specific embodiment, the plate defines a groove which is disposed around a fastener attached to the housing so that the plate is slideable relative to the housing.

Yet other aspects of the invention provide methods for promoting fusion bone growth between adjacent vertebrae. In one embodiment, a method includes providing the inventive spacers having an elongated body described above, preparing the adjacent vertebrae to receive the elongated body of the spacer in an intervertebral space between adjacent vertebrae and placing the body in the intervertebral space. In certain embodiments, two spacers can be bilaterally positioned.

The combination of the spacers of this invention with the tools and methods of this invention provide a versatile spacer without any compromise in biomechanical integrity. The spacers can be packed before or after implantation, preferably before.

Accordingly, it is one object of this invention to provide interbody fusion spacers and methods for using the spacers in an arthrodesis procedure.

Another object is to improve patient incidence of safe and satisfactory spinal stabilization and fusion.

Yet another object of the present invention is to provide spacers with good biomechanical features and osteogenic and fusion promoting features.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side perspective view of one embodiment of an interbody fusion spacer of the present invention.

FIG. 2 is a side perspective view of another embodiment of an interbody fusion spacer.

FIG. 3 is a top view of the spacer shown in FIG. 1.

FIG. 4 is a side perspective view of one embodiment of an interbody fusion implant system of the present invention.

FIG. 5 is a top view of the implant system of FIG. 4.

FIG. 6 is a side view of the implant system of FIG. 4.

FIG. 7 is a side perspective view of another embodiment of an interbody fusion implant system of the present invention.

FIG. 8 is a side perspective view of another embodiment of an interbody fusion implant system, showing spacers bilaterally placed with their chambers, or interior cavities, facing each other.

FIG. 9 is a top perspective view of one embodiment of an insertion tool of the present invention.

FIG. 10 is a side perspective view of the tool of FIG. 9.

FIG. 11 is a perspective view of a spacer engaging element of an insertion tool.

FIG. 12 is a perspective view of a spacer engaging element of an insertion tool.

FIG. 13 is a side elevational view of an insertion tool engaged to a spacer.

FIG. 14 is a top perspective view of the view shown in FIG. 13.

FIG. 15 is an exploded side perspective view of a tool-spacer assembly of the present invention.

FIG. 16 is a side perspective view of a tool-spacer assembly.

FIG. 17 is a top perspective view of a fastener of an insertion tool.

FIG. 18 is a top elevational view of the fastener of FIGS. 16 and 17.

FIG. 19 is a side elevational view of the fastener of FIG. 17.

FIG. 20 is a top elevational view of an implant system of the present invention implanted within an intervertebral space via an anterior surgical approach.

FIG. 21 is a top elevational view of another implant system described herein implanted within an intervertebral space via an anterior surgical approach.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

This invention provides interbody fusion spacers having side-openings preferably along with features allowing them to nest within each other, thus allowing close placement of one or more, typically a pair of, spacers within the intervertebral space. These spacers are advantageous for exposure of vertebral tissue to osteogenic material within the interior cavities. The design of these spacers conserves material without compromising biomechanical properties of the spacer, while allowing packing of the spacer with autologous bone chips or another suitable osteogenic or osteoconductive material through a side wall thereof. Accordingly, in one aspect of the invention, inventive interbody fusion spacers are provided that include discontinuities in side walls thereof, and preferably also that are configured for nesting with adjacent spacers. In other aspects of the invention, interbody fusion implant systems are provided that may include an interbody fusion spacer nested within another spacer, including one of the inventive interbody fusion spacers of the present invention. Other aspects of the invention include methods of promoting fusion bone growth in the space between adjacent vertebrae as well as inventive tools for placement of the spacers of the present invention.

Referring now to FIGS. 1 and 3, one embodiment of an interbody fusion spacer 1100 is shown. Spacer 1100 includes a body 1110 that is generally cylindrical in shape. Body 1110 includes an outer surface 1150, an end 1120 that defines end wall 1121 and an end 1130 that defines end wall

1131. Body 1110 further includes side wall 1140 that connects end 1120 and end 1130.

Body 1110 is generally hollow, defining a hollow interior cavity, or chamber, 1113. Osteogenic and/or osteoconductive material, as further described below, may advantageously be placed in interior cavity 1113. As further seen in FIG. 1, side wall 1140 defines an opening 1160, such as a side-access opening, to interior cavity 1113 in a side of body 1110. Interior cavity 1113 is in communication with opening 1160. Opening 1160 may thus provide access to interior cavity 1113 before or after implantation or can facilitate insertion of spacer 1100 into the intervertebral space. Due to the presence of the side-access opening 1160 of body 1110, its end walls can be optionally substantially closed, fixed and non-removable. For example, such end walls can be integral with the side walls. It is preferred that the wall that is inserted first into the intervertebral space, such as end wall 1131, is closed and may be positioned to protect the spinal cord from escape or leakage of any osteogenic material from interior cavity 1113 when the spacer is placed by an anterior approach.

As can further be seen in FIG. 1, at least one of the ends is advantageously configured for nesting with an adjacent spacer. In one preferred form of the invention, each of the ends has a concave discontinuity 1118. As can further be seen in FIG. 1, opening 1160 is further defined by discontinuity 1119 extending along the length of body 1110. The discontinuities advantageously expose surfaces that are configured to receive a surface of an adjacent spacer having a complimentary exterior profile. For example, the discontinuities may expose concave surfaces 1116 and 1117 of end walls 1121 and 1131, respectively. Nesting between adjacently-placed spacers may occur by having concave surfaces 1116 and 1117 receive an outer concave surface of an adjacent spacer. The ends are therefore configured such that when at least one of the spacers having a discontinuity is combined with another spacer to form an implant system, the width W_s of the

implant system is typically less than the sum of the combined maximum diameters D_M, $D_{M'}$ of the individual spacers, as best seen in FIG. 6.

In the preferred device, the discontinuity 1118 in the end walls of body 1100 will span at least about 10% of the circumference of the body 1100, more preferably at least about 20% of the circumference. Discontinuity 1118 will preferably not exceed about 50% of the circumference of the body, more preferably not exceeding about 40% of the circumference.

Thus, where the body is substantially circular in cross section as shown, end walls 1121 and 1131 and side wall 1140 will have external surfaces defining an external profile in the shape of an arc of a circle, extending no greater than about 324°C around the circle (90% of the circumference), more preferably no greater than about 288° around the circle (80% of the circumference). Correspondingly also, the arc defined by the end walls and side walls will preferably not be less than about 180° (50% of the circumference), and more preferably not less than about 216°. In the preferred devices, the remaining external profile of the end walls define a concave surface, configured for nesting with an adjacent spacer.

Discontinuity 1119 along the length of the body, which preferably extends substantially parallel to the longitudinal axis of body 1110, will preferably span at least about 50% of the length of the body, more preferably at least about 80%, and will most preferably span substantially the entire length of the side wall 1140. Moreover, the circumferences of the side wall and end walls desirably extend uniformly along the length of the body. Furthermore, in a preferred device, the side wall and end walls extend about the circumference of body 1110 to substantially the same extent.

Body 1110 further preferably includes a plurality of smaller openings 1115 for bone ingrowth. Openings 1115 preferably extend from outer surface 1150 of body 1110 into interior cavity 1113.

The spacers of the invention are typically sized, or configured, to fit within an intervertebral space. One skilled in the art is aware that the size will

depend on the specific circumstances, including the size of the recipient and the location in the spine into which the spacers will be positioned.

The spacers of the invention may be provided with surface features defined in outer surface 1150. A wide variety of surface features are contemplated. In one form of the invention, end 1120 is a tool engagement end that defines a tool engaging or instrument attachment hole 1111 as seen in FIG. 1. In a preferred embodiment, hole 1111 is threaded but any suitable configuration is contemplated.

Spacers of the present invention may further include a tool-engaging slot 1112 for receiving an implantation tool. The slot is typically perpendicular to the central longitudinal axis A_L of spacer 1100. In yet other embodiments, slot 1112 may form an alignment score mark or groove 1112' defined in tool engagement end 1120' of spacer 1100' as seen in FIG. 2, thus making the opposite end, where end wall 1130' is located, the insertion end. Spacer 1100' is identical in all respects to spacer 1100, except for the difference in the feature present on the end walls. Thus, components of spacer 1100' are numbered correspondingly to those of spacer 1100, except with a denoting prime (') symbol. Alternatively, a projection may be formed on the end walls instead of a slot. Such a projection may form a straight, flat-sided shape (such as a mirror image of the slot depicted in FIG. 1), an elliptical eminence, a bi-concave eminence, a square eminence, or any other protruding shape which provides sufficient end-cap or tool engaging end strength and drive purchase to allow transmission of insertional torque without breaking or otherwise damaging the eminence.

Yet other surface features can be defined along the length L of the spacer. Referring again to FIGS. 1 and 3, outer surface of spacer 1100 may defines threads 1114 as illustrated, and/or other expulsion-resisting proturbances. The threads may be made by methods and tools well known in the art. The threads provide many advantages. For example, the thread feature increases postoperative stability of the spacer by engaging the adjacent vertebral endplates and anchoring the spacer to prevent expulsion.

The threads also stabilize the bone-spacer interface and reduce micromotion to facilitate fusion.

Interior cavity 1113 may be packed with any suitable osteogenic or osteoconductive material. In a preferred embodiment, the material M is sized so that it will contact the endplates of the adjacent vertebrae when the spacer is implanted within the vertebrae. This provides better contact of the composition with the endplates to stimulate bone ingrowth. Osteogenic material may advantageously be disposed in interior cavity 1113 through side-access opening 1160. Thus, opening 1160 is preferably sized to allow passage of osteogenic material into the interior cavity,or chamber 1113.

Any suitable osteogenic or osteoconductive material or composition is contemplated, including autograft, allograft, xenograft, demineralized bone, synthetic and natural bone graft substitutes, such as bioceramics, polymers, and osteoinductive factors. The terms osteogenic material or osteogenic composition as used herein mean virtually any material that promotes bone growth or healing including autograft, allograft, xenograft, bone graft substitutes and natural, synthetic and recombinant proteins, hormones and the like.

Autograft can be harvested from locations such as the iliac crest using drills, gouges, curettes, trephines and other tools and methods which are well known to surgeons in this field. Preferably, autograft is harvested from the iliac crest with a minimally invasive donor surgery. The osteogenic material may also include bone reamed away by the surgeon while preparing the end plates for the spacer.

Advantageously, where autograft is chosen as the osteogenic material, only a very small amount of bone material is needed to pack the chamber. The autograft itself is not required to provide structural support as this is provided by the spacer. The donor surgery for such a small amount of bone is less invasive and better tolerated by the patient. There is usually little need for muscle dissection in obtaining such small amounts of bone. The present

invention therefore eliminates or minimizes many of the disadvantages of employing autograft.

Natural and synthetic graft substitutes which replace the structure or function of bone are also contemplated for the osteogenic composition. Any such graft substitute is contemplated, including for example, demineralized bone matrix, mineral compositions and bioceramics. As is evident from a review of *An Introduction to Bioceramics*, edited by Larry L. Hench and June Wilson (World Scientific Publishing Co. Ptd. Ltd, 1993, volume 1), there is a vast array of bioceramic materials, including BIOGLASS®, hydroxyapatite and calcium phosphate compositions known in the art which can be used to advantage for this purpose. That disclosure is herein incorporated by reference for this purpose. Preferred compositions include bioactive glasses, tricalcium phosphates and hydroxyapatites. In one embodiment, the graft substitute is a biphasic calcium phosphate ceramic including tricalcium phosphate and hydroxyapatite.

In some embodiments, the osteogenic compositions used in this invention may comprise a therapeutically effective amount to stimulate or induce bone growth of a substantially pure bone inductive or growth factor or protein in a pharmaceutically acceptable carrier. The preferred osteoinductive factors are the recombinant human bone morphogenetic proteins (rhBMPs) because they are available in unlimited supply and do not transmit infectious diseases. Most preferably, the bone morphogenetic protein is a rhBMP-2, rhBMP-4 or heterodimers thereof.

Recombinant BMP-2 can be used at a concentration of about 0.4 mg/ml to about 1.5 mg/ml, preferably near 1.5 mg/ml. However, any bone morphogenetic protein is contemplated including bone morphogenetic proteins designated as BMP-1 through BMP-13. BMPs are available from Genetics Institute, Inc., Cambridge, Massachusetts and may also be prepared by one skilled in the art as described in U.S. Patent Nos. 5,187,076 to Wozney et al.; 5,366,875 to Wozney et al.; 4,877,864 to Wang et al.; 5,108,922 to Wang et al.; 5,116,738 to Wang et al.; 5,013,649 to Wang et al.;

5,106,748 to Wozney et al.; and PCT Patent Nos. WO93/00432 to Wozney et al.; WO94/26893 to Celeste et al.; and WO94/26892 to Celeste et al. All osteoinductive factors are contemplated whether obtained as above or isolated from bone. Methods for isolating bone morphogenetic protein from bone are described, for example, in U.S. Patent No. 4,294,753 to Urist and Urist et al., 81 PNAS 371, 1984.

The choice of carrier material for the osteogenic composition is based on biocompatibility, biodegradability, mechanical properties and interface properties as well as the structure of the load bearing member. The particular application of the compositions of the invention will define the appropriate formulation. Potential carriers include calcium sulphates, polylactic acids, polyanhydrides, collagen, calcium phosphates, polymeric acrylic esters and demineralized bone. The carrier may be any suitable carrier capable of delivering the proteins. Most preferably, the carrier is capable of being eventually resorbed into the body. One preferred carrier is an absorbable collagen sponge marketed by Integra LifeSciences Corporation under the trade name Helistat® Absorbable Collagen Hemostatic Agent. Another preferred carrier is a biphasic calcium phosphate ceramic. Ceramic blocks are commercially available from Sofamor Danek Group, B. P. 4-62180 Rang-du-Fliers, France and Bioland, 132 Rou d Espangne, 31100 Toulouse, France. The osteoinductive factor is introduced into the carrier in any suitable manner. For example, the carrier may be soaked in a solution containing the factor.

In another aspect of the invention, an interbody fusion implant system is provided. The system includes one of the inventive spacers described above, along with either another of the inventive spacers, or with other spacers known to the art. Referring now to FIGS. 4-6, implant system 1300 may include spacer 1100 combined with an adjacent spacer 1200 to provide a nested implant system. Spacer 1200 is of a design similar to that of spacer 1100 having all the features thereof, except it does not have the wall discontinuities. Thus, spacer 1200 preferably has either a removable or non-

removable end wall, or cap, 1221, more preferably in the tool engaging end 1220. Moreover, spacer 1200 may include, for example, instrument attachment hole 1211, tool engaging slot 1212, side wall 1240, outer surface 1250, openings 1215 for bone ingrowth, end walls 1221 and 1231, internal cavity 1213 and threads 1214. It is also seen that the width W_s of system 1300 is less than the sum of the maximum diameter D_M of spacer 1100 and the maximum diameter $D_{M'}$ of spacer 1200. Such is the preferred configuration present in the implant systems described herein. In yet other forms of the invention as depicted in FIG. 7, two spacers 1100 can be placed adjacent to one another to provide implant system 1400.

In yet another embodiment, two spacers 1100 can optionally be aligned such that the side-wall openings 1160 face one another as seen in FIG. 8, thus forming implant system 1400'. The spacers are of the invention can be formed of any suitable biocompatible material, including metals, ceramics, polymers, composites, and alloys. A preferred material includes metals, including metal alloys. Some embodiments include titanium, stainless steel, and Hedrocel®.

The spacers described herein may be conveniently implanted with known instruments and tools. Any instrument which will firmly hold the implant and permit the implant to be inserted is contemplated. Preferably, the instrument will be adapted to compensate for the open structure of the inventive spacers described herein.

Accordingly, yet another aspect of the invention provides insertion devices for facilitating the implantation of spacers, implants and osteogenic material. The tools include spacer engaging means for engaging a spacer or other item and occlusion means for blocking an opening defined in the spacer.

Referring now to FIGS. 9-12, one embodiment of an insertion tool 800' is provided which includes a housing 805' having a proximal end 806' and an opposite distal end 807' and defining a passageway 810' between the two ends. A shaft 815' which has a first end 816' and an opposite second end 817' is disposed within the passageway 810'. The first end 816' of the shaft

815' is adjacent the distal end 807' of the housing 805'. The first end 816 defines a spacer engager 819'. An occlusion member 820' is attached to the housing 805'.

The spacer engager 819' has any configuration which will engage a spacer. In some embodiments the spacer engager 819' includes a post 818' as shown in FIG. 11 for engaging a hole in the spacer. The post 818' may have any configuration which will provide for mating engagement with a hole in a spacer. For example, in preferred embodiments, the engager 819' is threaded as shown in Figure 11 to matingly engage a threaded tool hole. Other embodiments include sharply pointed tip 819' as shown in Figure 9 or a hexagonal shaped tip 819" as shown in FIG. 12. In each case, the engager is shaped and sized to mate engagingly with the tool hole of the spacer. In other embodiments, the spacer engaging means is a pair of prongs having opposite facing spacer engaging members for grasping an outer surface of the spacer.

The spacer insertion tool 800' also includes an occlusion member 820' for blocking an opening defined in the spacer when the spacer engager 819' is engaged to the spacer. In a preferred embodiment, the occlusion member 820' is extendible from the distal end 807' of the housing 805' for blocking an opening in the spacer. As shown in Figure 13, the occlusion member 820' closes the opening 1160 to interior cavity 1113 of spacer 1100.

The occlusion member 820' is preferably slideably engaged to the housing 805'. Referring now to Figure 14, in one embodiment, the occlusion member 820' includes a plate 821' which defines a groove 822'. A fastener 830' is engaged to a fastener bore 809' (seen in FIG. 10) in the housing 805' and the groove 822' is disposed around the fastener 830'. In this way, the plate 821' is slideable relative to the housing 805'.

As shown in FIG. 15, the housing 805' is preferably provided with a recess 808' which is defined to accept the occlusion member 820' without increasing the effective diameter of the device 800'. The occlusion member is also adapted for the best fit with the spacer. For example, the interior surface

824' of the occlusion member is preferably curved to complement the concave-shaped discontinuity of the inventive spacers described herein. Referring now to FIGS.15 and 16, the plate 821' of the occlusion member 820' preferably includes a curved superior surface 825' which approximates and completes the minor diameter of spacer 1100 when the spacer engager 819' is engaged to the tool engaging hole 1111 and the occlusion member 820' is blocking opening 1160 of spacer 1100. Preferably, the plate 821' and the end walls 1121 and 1131 of spacer 1100 will be configured such that curved superior surface 825' will not increase the maximum diameter D_M of the threaded outer surface 1150 when the tool is engaged to the spacer. This facilitates rotation and screw insertion of the spacer and occlusion member combination into an intervertebral space. The occlusion member 820' preferably has an interior surface 824' which is convexly curved to complement the concave surfaces of end walls 1121 and 1131 of spacer 1100. Correspondingly, recess 808' of insertion tool 800' has a concave surface complementary to convexly curved surface 824' of occlusion member 820'. Further, occlusion member 820' is of a length and design sufficient to span to the distal end of the engaged spacer 1100, as depicted in Figure 13. Occlusion member 820' can also have a beveled outer end as depicted, or an otherwise smoothed outer end, to facilitate rotary insertion.

The tool 800' depicted in Figure 9 also includes a handle portion 840'. The handle portion includes means for slidingly moving the shaft 815' within the housing 805' and for rotating the post 818'. In the embodiment shown in FIGS. 9 and 10 the means includes a thumbwheel 841'. In some embodiments, the handle portion 840' has a Hudson end attachment 842'.

Referring now to FIGS. 17-19, the fastener 830' is preferably provided with a housing engaging means shown in FIG. 17 as a post 834', and a plate engaging means or head portion 835'. The fastener 830' preferably includes an internal hex 837' for receiving a fastener driving tool. The post portion 834' may be threaded for mating engagement with threaded bore 809' in the housing 805'. In preferred embodiments shown in FIGS. 14 and 16, the plate

821' defines a recess 826 surrounding the groove 822'. The diameter d_1 of the head portion 835 is greater than the diameter d2 of the post 834'. The diameter d_2 is less than the width w_1 of the groove 822'. The diameter d_1 of the head portion is greater than width w_1 but preferably no greater than the distance w_2 between the outer edges 827' of the recess 826'. Thus, the head portion 835' of the fastener 830 can rest on the recess 826 while the post portion 834' extends through the groove 822'. In this way, plate 821' is slidable relative to the housing 805'. This also provides for a low profile device which can be inserted into various cannula for percutaneous procedures.

The spacers and tools in this invention can be conveniently incorporated into known surgical, preferably minimally invasive, procedures. The spacers of this invention can be inserted using laparoscopic technology as described in Sofamor Danek USA's Laparoscopic Bone Dowel Surgical Technique, 1995, 1800 Pyramid Place, Memphis, Tennessee 38132, 1-800-933-2635, preferably in combination with the insertion tool 800' of this invention.

The combination of spacers of this invention with the tools of this invention allow the spacers to provide the benefits of a nestable spacer without suffering any biomechanical disadvantage. The occlusion member 825' blocks the side-opening of the spacer to lessen the stress on the wall of the spacer for smooth insertion. The occlusion member also allows the chamber, or interior cavity, to be packed with osteogenic material before the spacers are implanted. In some procedures, two open spacers are packed with their side-openings facing one another as depicted in Figure 8. The side-opening of the spacers, along with the tools described herein, allow the spacers to be packed closely together because virtually no clearance is required for the insertion tool. The side-opening also allows the interior cavity to be packed after the spacer is implanted.

In other aspects of the invention, methods of promoting fusion bone growth in the space between adjacent vertebrae are provided. In one form of

the invention, the method includes providing a first interbody fusion spacer described herein, such as one in which each end has a surface for nesting with an adjacent spacer and having a first side wall defining an opening to the interior cavity in a side of the spacer body. The spacer selected is of the appropriate dimensions, based on the size of the cavity created and the needs of the particular patient undergoing the fusion. The adjacent vertebrae are prepared to receive the spacer in an intervertebral space between adjacent vertebrae according to conventional procedures. The spacer is mounted on an instrument, preferably via an instrument attachment hole. An osteogenic material may optionally be placed within the cavity of the spacer and the opening of the spacer is then blocked with an occlusion member of the instrument. The spacer is then inserted into the cavity created between the adjacent vertebrae to be fused. Once the spacer is properly oriented within the intervertebral space, the occlusion member of the instrument can be withdrawn form the spacer aperture and the spacer engager is disengaged from the spacer. In a preferred form of the invention, a second spacer is inserted into the intervertebral space after the first spacer is properly positioned near vertebral body V, resulting in bilateral placement of the spacers as seen in FIG. 20. The second spacer may be the same as the first spacer, as seen in FIG. 20 with two spacers 1100 that form implant system 1400, or may be any other spacer described herein or other appropriate spacer known in the art. To this end, implant systems 1300, 1400, or 1500, for example, may be advantageously used in the present invention. Osteogenic material may also optionally be placed within those spacers having chambers therein.

Bilateral placement has many advantages. For example, bilateral placement results in improved spinal support with two spacers that fit properly within the disc space. Moreover, such positioning allows for a substantial area for placement of osteogenic material which will facilitate boney bridging across the disc space, especially when the spacers are positioned with their

side wall openings facing each other as seen in FIG. 21 with spacers 1100 that form implant system 1400'.

It should be understood that the embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and the scope of the appended claims.

CLAIMS

What is claimed is:

1. An interbody fusion spacer, comprising:

an elongated body having a first end, a second end, an outer surface and a side wall connecting said first end and said second end, said elongated body defining an interior cavity;

at least one of said first end and said second end having an end wall discontinuity configured for nesting with an adjacent spacer; and

said side wall defining a side wall opening to said interior cavity in a side of said elongated body.

2. The spacer of claim 1, wherein said body is comprised of metal.

3. The spacer of claim 1, wherein said body is generally cylindrical in shape.

4. The spacer of claim 1, wherein said outer surface defines threaded bone-engaging portions.

5. The spacer of claim 1, wherein said side wall defines a plurality of openings for bone ingrowth extending from said outer surface into said internal cavity.

6. The spacer of claim 1, wherein one of said ends comprises a tool engaging end defining a tool engaging hole for receiving a driving tool for implanting the spacer.

7. The spacer of claim 1, further comprising an osteogenic material disposed within said cavity.

8. The spacer of claim 7, wherein said osteogenic material comprises demineralized bone, a calcium phosphate material, a bioceramic, bioglass, an osteoinductive factor and mixtures thereof.

9. The spacer of claim 1, wherein said side wall opening is defined by a side wall discontinuity in said side wall that extends over at least about 10% of the circumference of said body but not exceeding about 50% of the circumference of said body.

10. The spacer of claim 9, wherein said side wall discontinuity extends over at least about 20% of the circumference of said body but not exceeding about 40% of the circumference of said body.

11. The spacer of claim 1, wherein said side wall opening is defined by a side wall discontinuity that extends over at least about 50% of the length of said body.

12. The spacer of claim 11, wherein said side wall discontinuity extends over at least about 80% of the length of said body.

13. The spacer of claim 1, wherein said side wall opening is sized to allow passage of osteogenic material into said interior cavity.

14. The spacer of claim 1, wherein said end wall discontinuity defines a concave surface.

15. The spacer of claim 1, wherein said end wall discontinuity is configured for nesting with an adjacent spacer.

16. The spacer of claim 1, comprising a side wall discontinuity aligned with said end wall discontinuity, said side wall discontinuity extending along the length of said body to define said opening in a side of said body.

17. The spacer of claim 1, having a concave end wall discontinuity at each of said first and second ends, and wherein each of said ends is configured to receive an outer convex surface of an adjacent spacer.

18. The spacer of claim 1, wherein each of said ends are configured for nesting with an adjacent spacer to form a spacer assembly having a width less than the sum of the combined maximum diameters of said spacers.

19. An interbody fusion spacer, comprising:

an elongated body having a circumference, a first end defining a first end wall, a second end defining a second end wall, an outer surface and a side wall connecting said first end and said second end, said elongated body defining an interior cavity, at least one of said end walls having a discontinuity configured for nesting with an adjacent spacer; said side wall defining a discontinuity extending along a length of said body, said discontinuity in said side wall defining an opening in communication with said interior cavity, said discontinuity in side wall being at a location corresponding to said discontinuity in said end wall, and said discontinuity in said end wall and said discontinuity in said side wall both extending about said circumference of said body to substantially the same extent.

20. An interbody fusion implant system, comprising:

a first interbody fusion spacer having a first elongated body having a first end, a second end, an outer surface and a side wall connecting said first end and said second end, said elongated body defining an interior cavity;

at least one of said first end and said second end having a discontinuity configured for nesting with an adjacent spacer,

said side wall defining an opening to said interior cavity in a side of said elongated body, said opening configured for loading said interior cavity with an osteogenic material; and

a second interbody fusion spacer having a second elongated body, said second elongated body having a third end, a fourth end, a second outer surface and a second side wall connecting said first end and said second end, said second interbody fusion spacer nestable within said first interbody fusion spacer.

21. The implant system of claim 20, wherein said first and second elongated bodies are comprised of metal.

22. The implant system of claim 20, wherein said first and second elongated bodies are generally cylindrical in shape.

23. The implant system of claim 20, wherein said first and second outer surfaces each independently define threaded bone-engaging portions.

24. The implant system of claim 20, wherein each of said elongated bodies further include a plurality of openings for bone ingrowth.

25. The implant system of claim 20, wherein one of said ends of said first body and one of said ends of said second body comprise a tool engaging end defining a tool engaging hole for receiving a driving tool for implanting the spacers.

26. The implant system of claim 20, further comprising an osteogenic material disposed within said first interior cavity.

27. The implant system of claim 26, wherein said osteogenic material comprises demineralized bone, a calcium phosphate material, a bioceramic, bioglass, an osteoinductive factor and mixtures thereof.

28. The implant system of claim 20, wherein said opening is defined by a discontinuity in said side wall over at least about 10% of the circumference of said body but not exceeding about 50% of the circumference of said first body.

29. The implant system of claim 28, wherein said discontinuity extends over at least about 20% of the circumference of said body but not exceeding about 40% of the circumference of said first body.

30. The implant system of claim 20, wherein said opening is defined by a discontinuity in said side wall extending over at least about 50% of the length of said first body.

31. The implant system of claim 30, wherein said discontinuity extends over at least about 80% of the length of said first body.

32. The implant system of claim 20, wherein said opening is sized to allow passage of osteogenic material into said first interior cavity.

33. The implant system of claim 20, wherein said second elongate body defines a second interior cavity.

34. An interbody fusion implant system, comprising:

a first interbody fusion spacer having a first elongated body, said first elongated body having a circumference, a first end defining a first end wall, a second end defining a second end wall, a first outer surface and a first side wall connecting said first end and said second end, said first elongated

body defining a first interior cavity, at least one of said end walls having a discontinuity configured for nesting with an adjacent spacer, said discontinuity extending along a length of said body and into said side wall, said discontinuity in said side wall defining an opening in communication with said first interior cavity, said side wall having said discontinuity and said end wall having said discontinuity both extending about said circumference of said body to substantially the same extent; and

a second interbody fusion spacer having a second elongated body, said second elongated body having a third end, a fourth end, a second outer surface and a second side wall connecting said third end and said fourth end, said second interbody fusion spacer nestable within said first interbody fusion spacer.

35. The implant system of claim 34, wherein at least one of said ends of said first interbody fusion spacer and said second interbody fusion spacer comprise a tool engaging end defining a tool engaging hole for receiving a driving tool for implanting the spacers.

36. The implant system of claim 34, wherein said first interbody fusion spacer and said second interbody fusion spacer are comprised of metal.

37. The implant system of claim 34, wherein said first elongated body has a first plurality of openings for bone ingrowth extending from said first outer surface into said first internal cavity,

38. A spacer insertion tool, comprising:

a housing having a proximal end and an opposite distal end and defining a passageway between said proximal end and said distal end;

a shaft having a first end and an opposite second end, said shaft disposed within said passageway with said first end adjacent said distal end, said first end defining a spacer engager; and

an occlusion member extendible from said distal end of said housing for blocking an opening defined in the spacer when said spacer engager is engaged to the spacer, said occlusion member having an interior and exterior surface, at least one of said surfaces of said occlusion member being curved.

39. The spacer insertion tool of claim 38, wherein both of said surfaces of said occlusion member are curved.

40. A method of promoting fusion bone growth in the space between adjacent vertebrae, comprising:

(a) providing a first interbody fusion spacer having a first elongated body, said first elongated body having a first end, a second end, a first outer surface and a first side wall connecting said first end and said second end, said elongated body defining a first interior cavity;

at least one of said first end and said second end having a discontinuity configured for nesting with an adjacent spacer;

said first side wall defining an opening to said interior cavity in a side of said first elongate body;

a second interbody fusion spacer having a second elongated body, said second elongated body having a third end, a fourth end, a second outer surface and a second side wall connecting said first end and said second end, said second interbody fusion spacer nestable within said first interbody fusion spacer;

(b) preparing said adjacent vertebrae to receive the elongated body in an intervertebral space between adjacent vertebrae; and

(c) placing the first elongated body into the intervertebral space.

41. The method of claim 40, further comprising packing osteogenic material into said interior cavity of said first spacer prior to the placing step.

42. The method of claim 40, further comprising implanting a second spacer into the intervertebral space after the placing step.

43. The method of claim 42, further comprising orienting said second spacer so that it nests within said first spacer.

44. The method of claim 40, wherein said first and second interbody fusion spacers are comprised of metal.

45. The method of claim 40, wherein said first elongated body has a first plurality of openings for bone ingrowth extending from said first outer surface into said first interior cavity.

46. A method of promoting fusion bone growth in the space between adjacent vertebrae, comprising:

(a) providing a first interbody fusion spacer having a first elongated body, said first elongated body having a circumference, a first end defining a first end wall, a second end defining a second end wall, a first outer surface and a first side wall connecting said first end and said second end, said first elongated body defining a first interior cavity, at least one of said end walls having a discontinuity configured for nesting with an adjacent spacer, said discontinuity extending along a length of said body and into said side wall, said discontinuity in said side wall defining an opening in communication with said first interior cavity, said side wall having said discontinuity and said end wall having said discontinuity both extend about said circumference of said body to substantially the same extent;

(b) preparing said adjacent vertebrae to receive the elongated body in an intervertebral space between adjacent vertebrae; and

(c) placing the first elongated body into the intervertebral space.

47. The method of claim 46, further comprising packing osteogenic material into said interior cavity of said first spacer prior to the placing step.

48. The method of claim 46, further comprising implanting a second spacer into the intervertebral space after the placing step.

49. The method of claim 48, further comprising orienting said second spacer so that it nests within said first spacer.

50. The method of claim 49, wherein said first and second interbody fusion spacers are comprised of metal.

51. The method of claim 50, wherein said first elongated body has a first plurality of openings for bone ingrowth extending from said first outer surface into said interior cavity.

52. An interbody fusion spacer, comprising:

an elongate body having end walls and a side wall extending between said end walls, said side wall and said end walls defining an interior cavity;

said end walls each having an external profile comprising a first portion defining an arc of a circle, said arc extending from 180° to 324° around the circle; said external profile also comprising a second portion defining a concave surface;

(b) preparing said adjacent vertebrae to receive the elongated body in an intervertebral space between adjacent vertebrae; and

(c) placing the first elongated body into the intervertebral space.

47. The method of claim 46, further comprising packing osteogenic material into said interior cavity of said first spacer prior to the placing step.

48. The method of claim 46, further comprising implanting a second spacer into the intervertebral space after the placing step.

49. The method of claim 48, further comprising orienting said second spacer so that it nests within said first spacer.

50. The method of claim 49, wherein said first and second interbody fusion spacers are comprised of metal.

51. The method of claim 50, wherein said first elongated body has a first plurality of openings for bone ingrowth extending from said first outer surface into said interior cavity.

52. An interbody fusion spacer, comprising:

an elongate body having end walls and a side wall extending between said end walls, said side wall and said end walls defining an interior cavity, said side walls further defining an opening configured for passage of osteogenic material into said cavity;

said end walls each having an external profile comprising a first portion defining an arc of a circle, said arc extending from 180° to 324° around the circle; said external profile also comprising a second portion defining a concave surface;

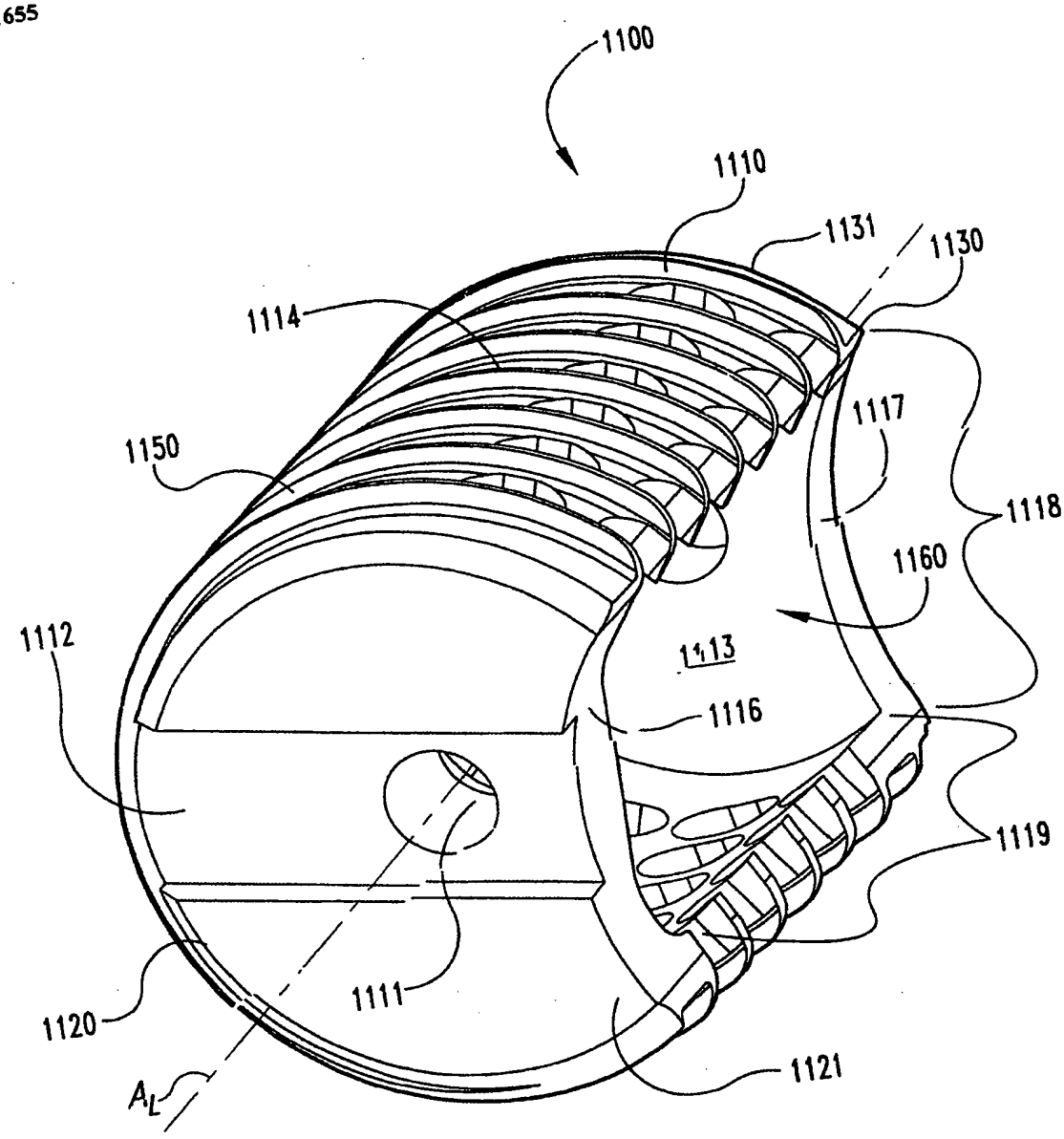

1100
1110
1131
1130
1114
1150
1117
1118
1160
1112
1113
1116
1119
1111
1120
1121
A_L

Fig. 1

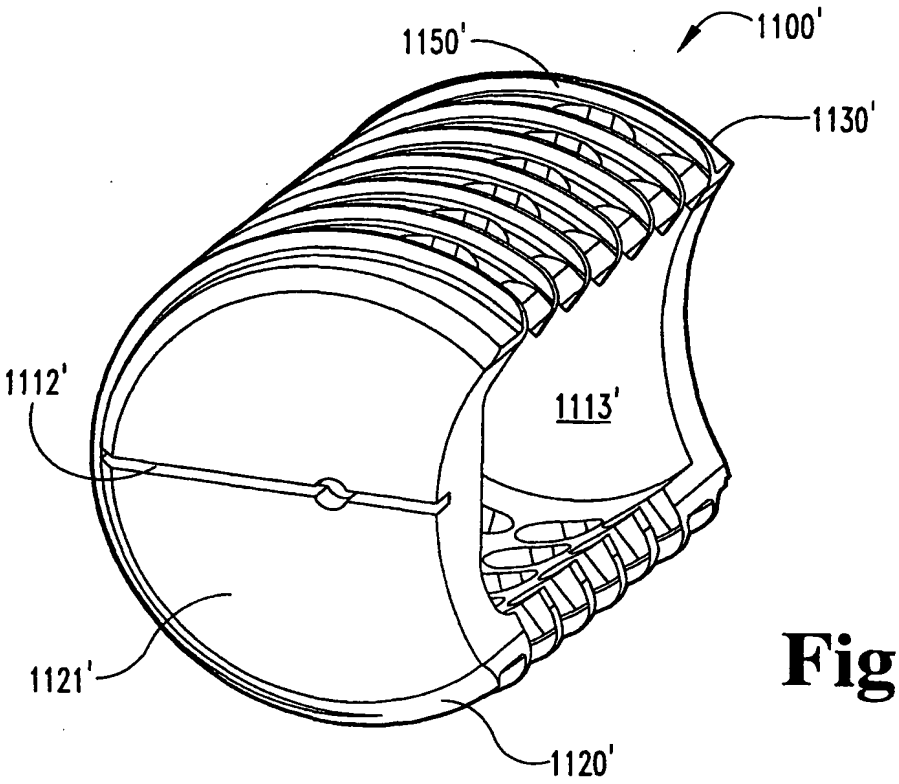

1150'
1100'
1130'
1112'
1113'
1121'
1120'

Fig. 2

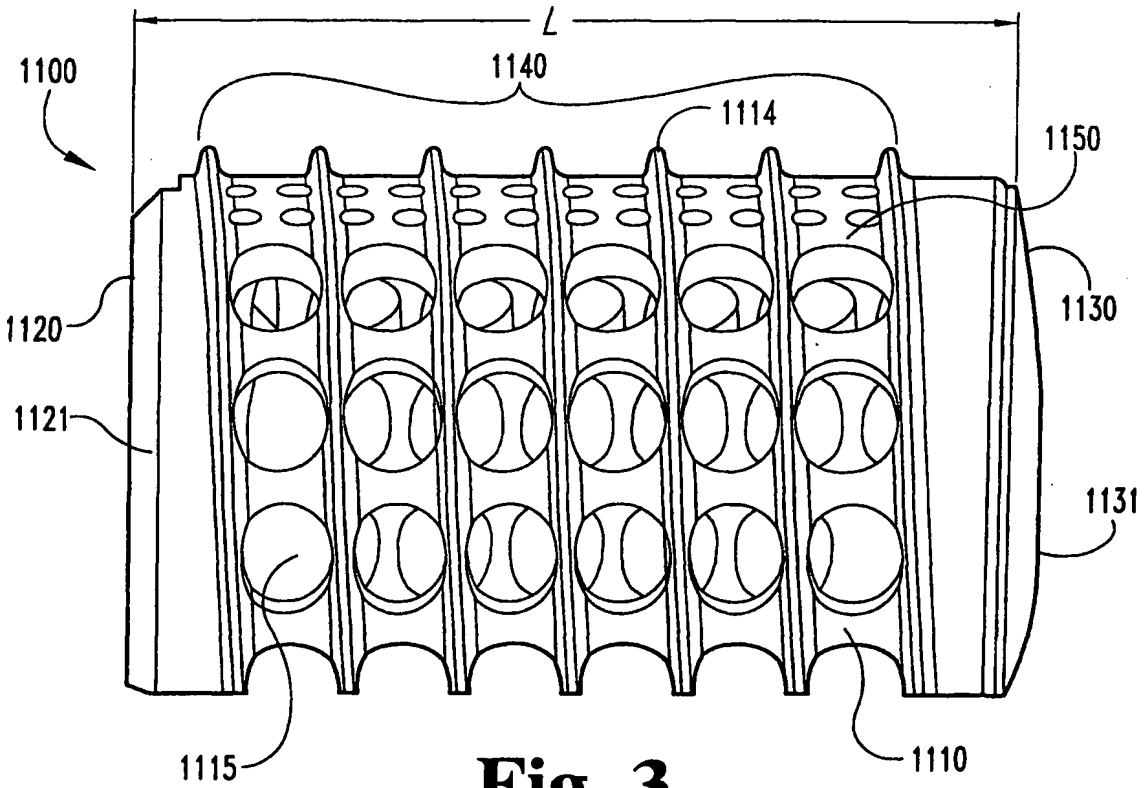

L
1100
1140
1114
1150
1120
1130
1121
1131
1115
1110

Fig. 3

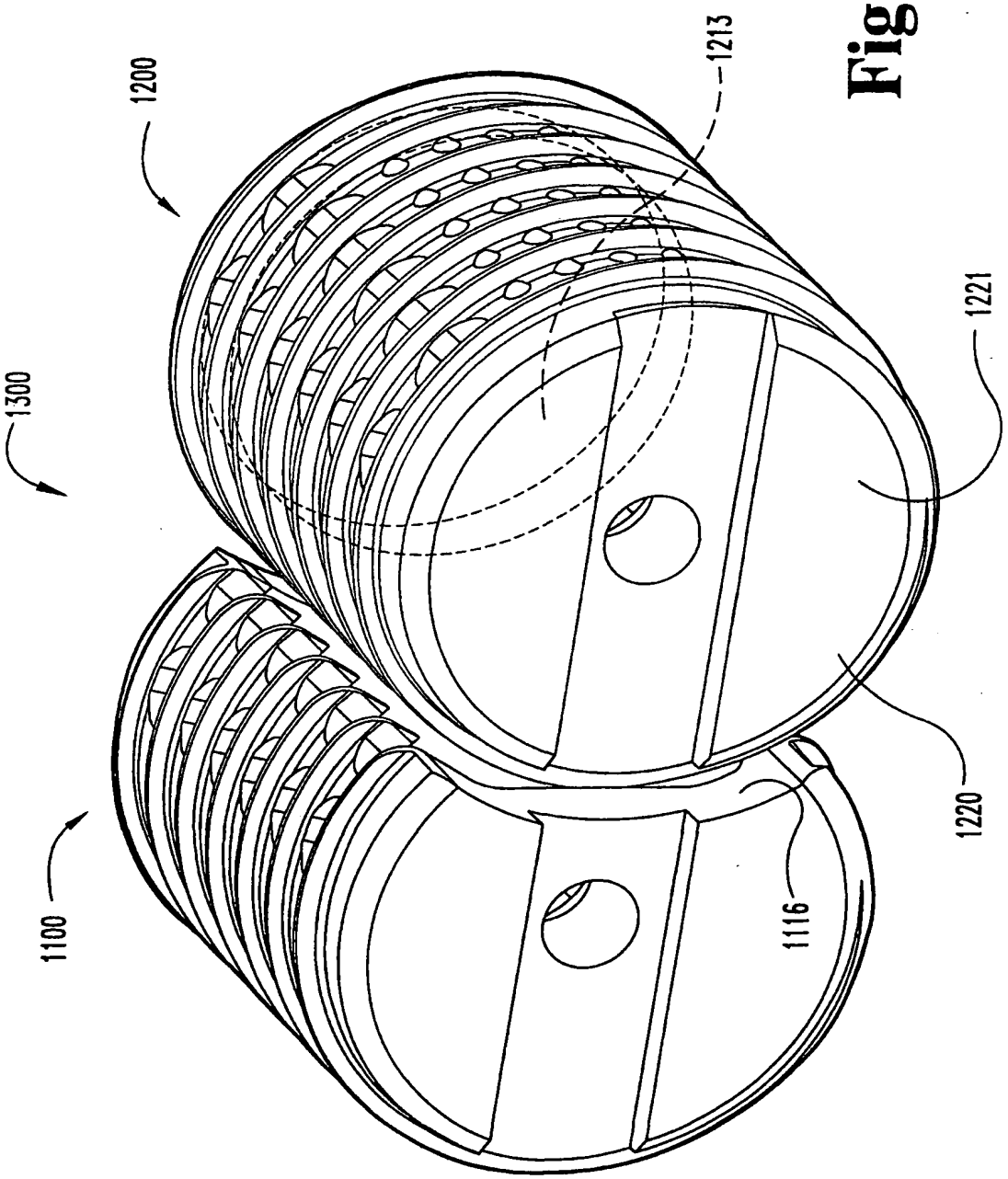


Fig. 4

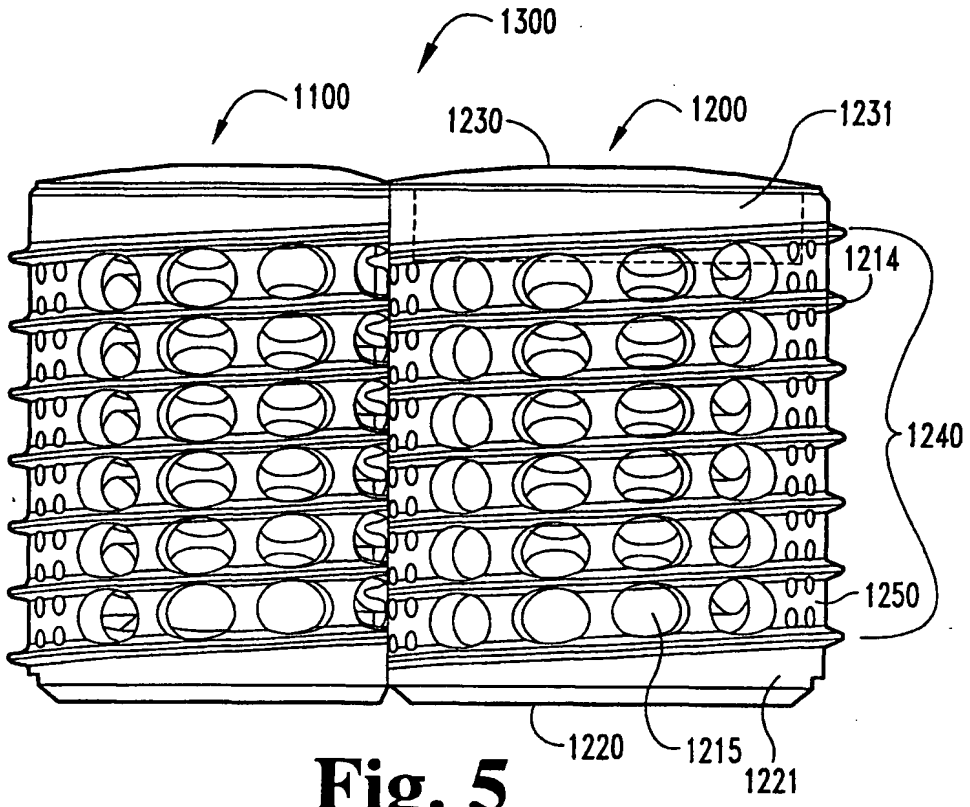

1300
1100
1230
1200
1231
1214
1240
1250
1220
1215
1221

Fig. 5

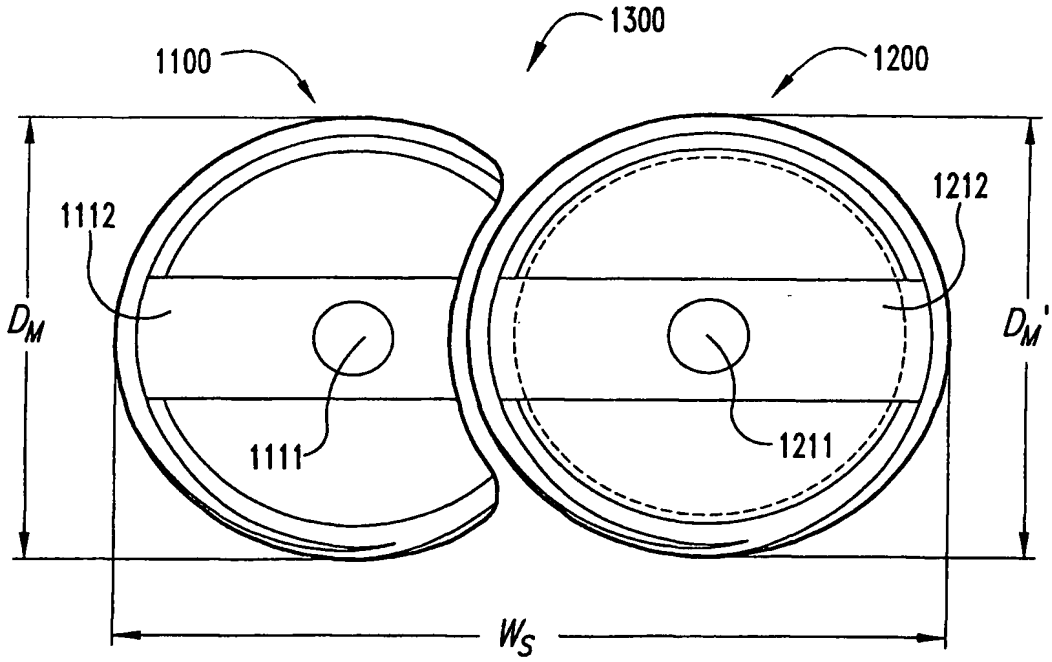

1300
1100
1200
1112
1212
D_M
D_M'
1111
1211
W_S

Fig. 6

Fig. 7

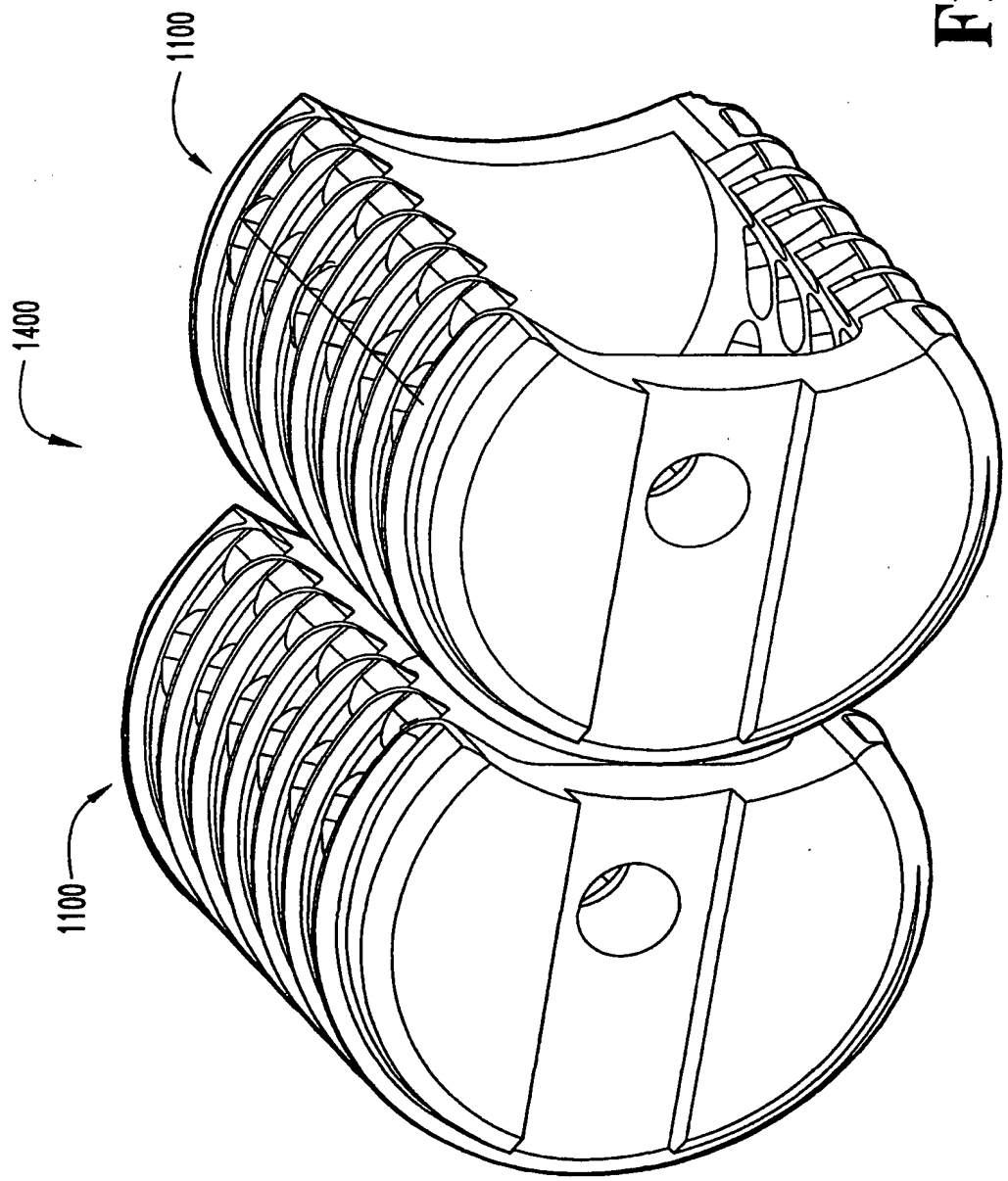
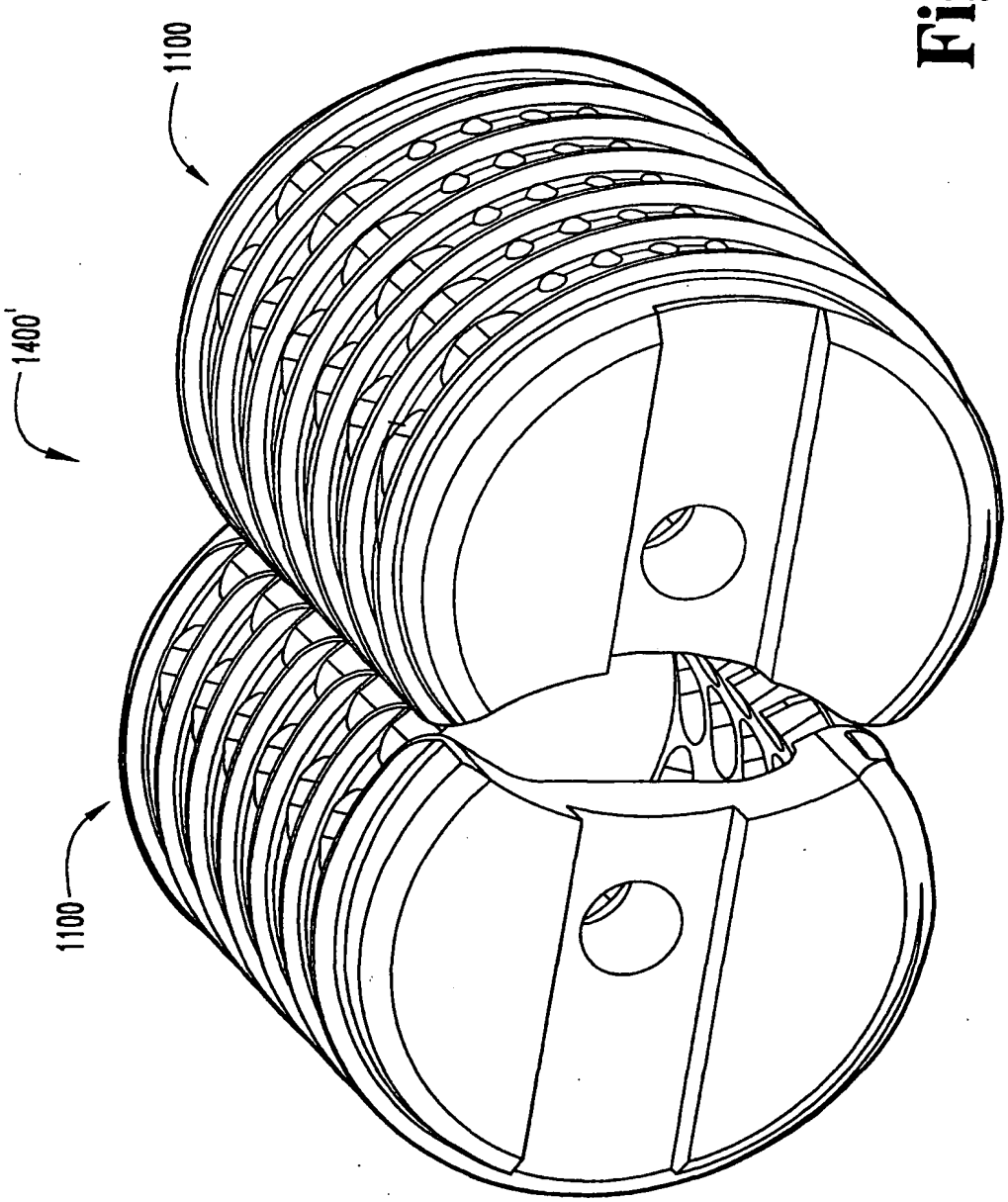


Fig. 8



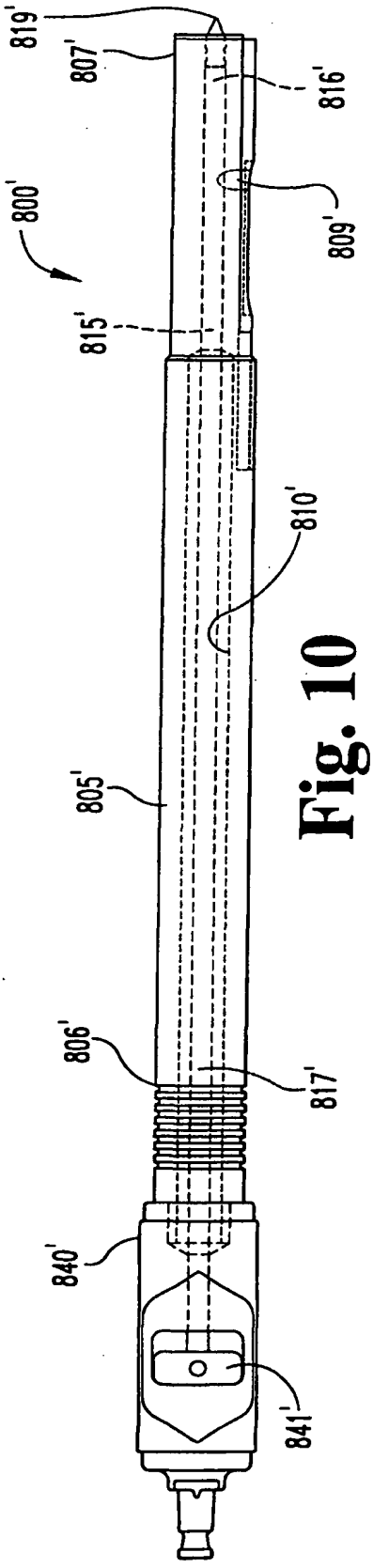

819'
807'
816'
800'
809'
815'
810'
805'
806'
817'
840'
841'

Fig. 10

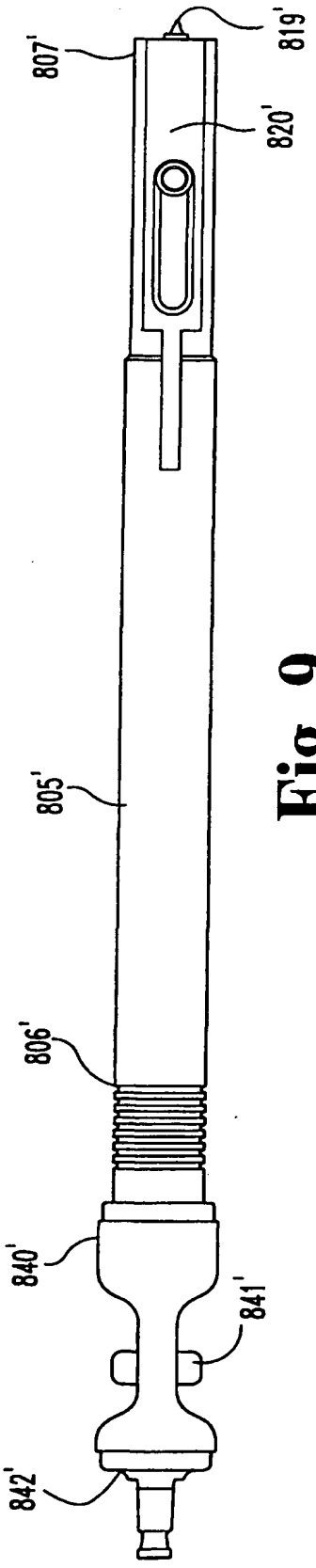

807'
819'
820'
805'
806'
840'
841'
842'

Fig. 9

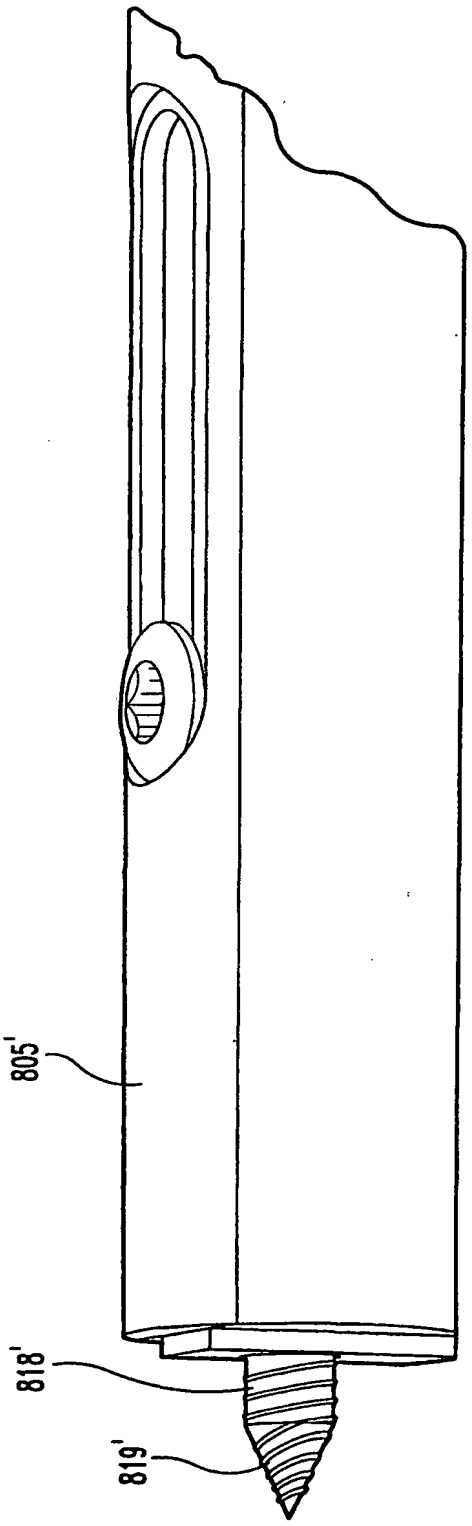


Fig. 11

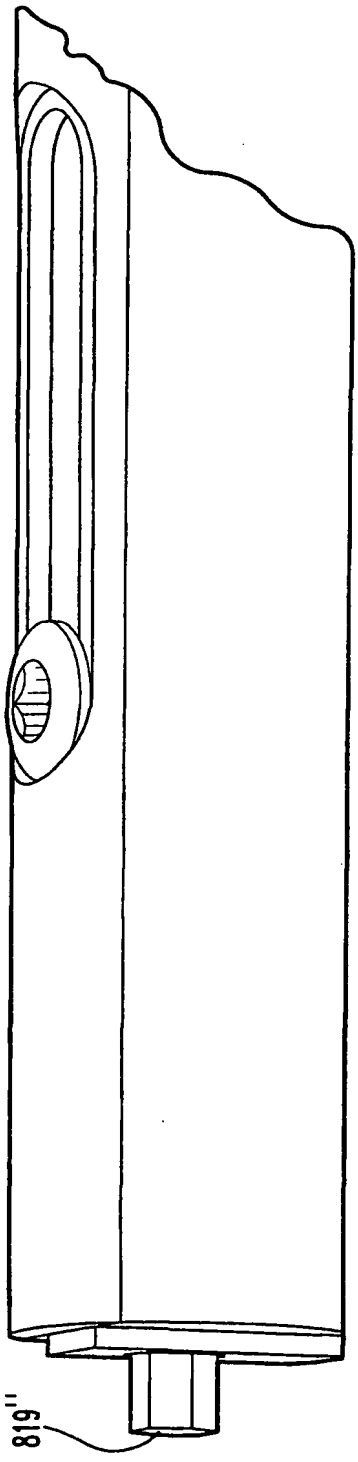


Fig. 12

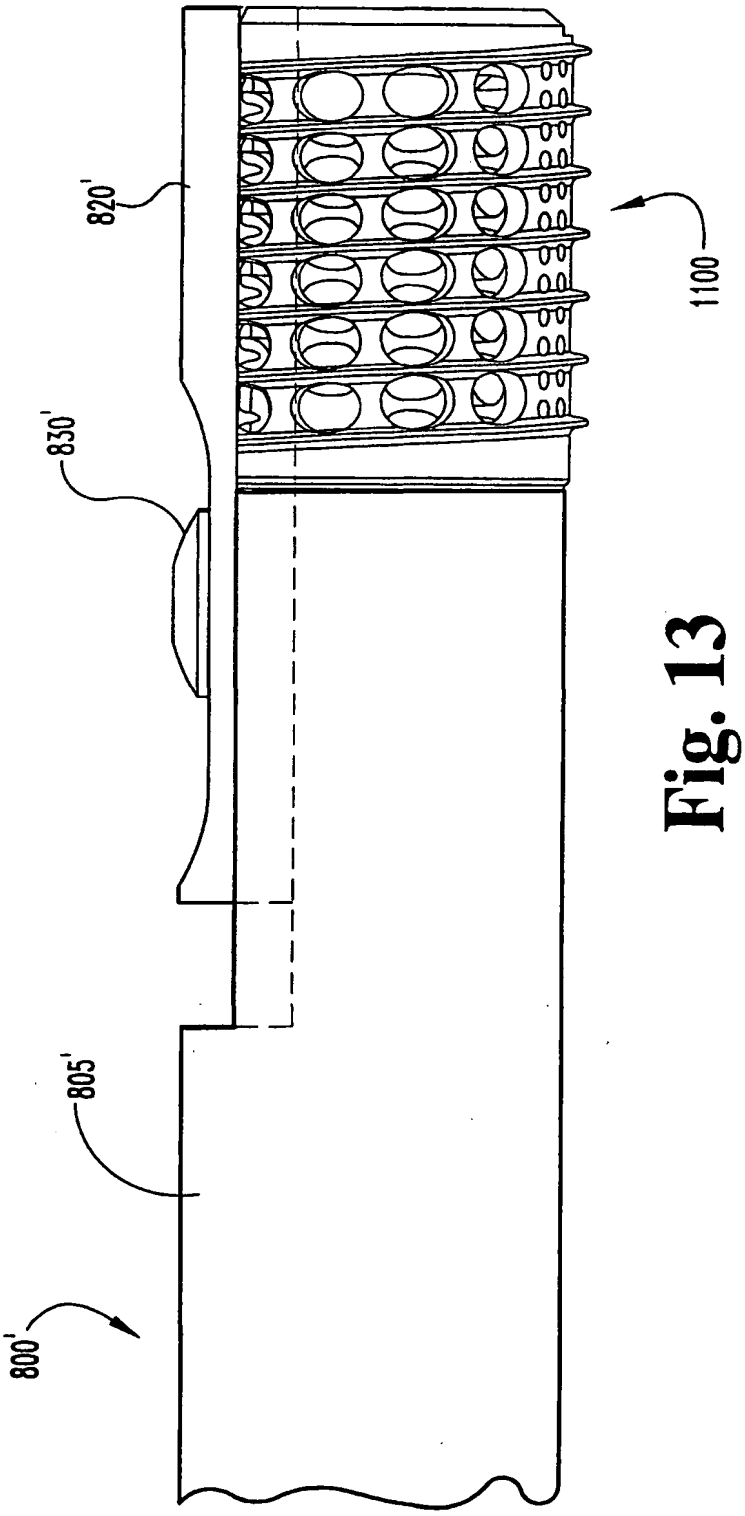


Fig. 13

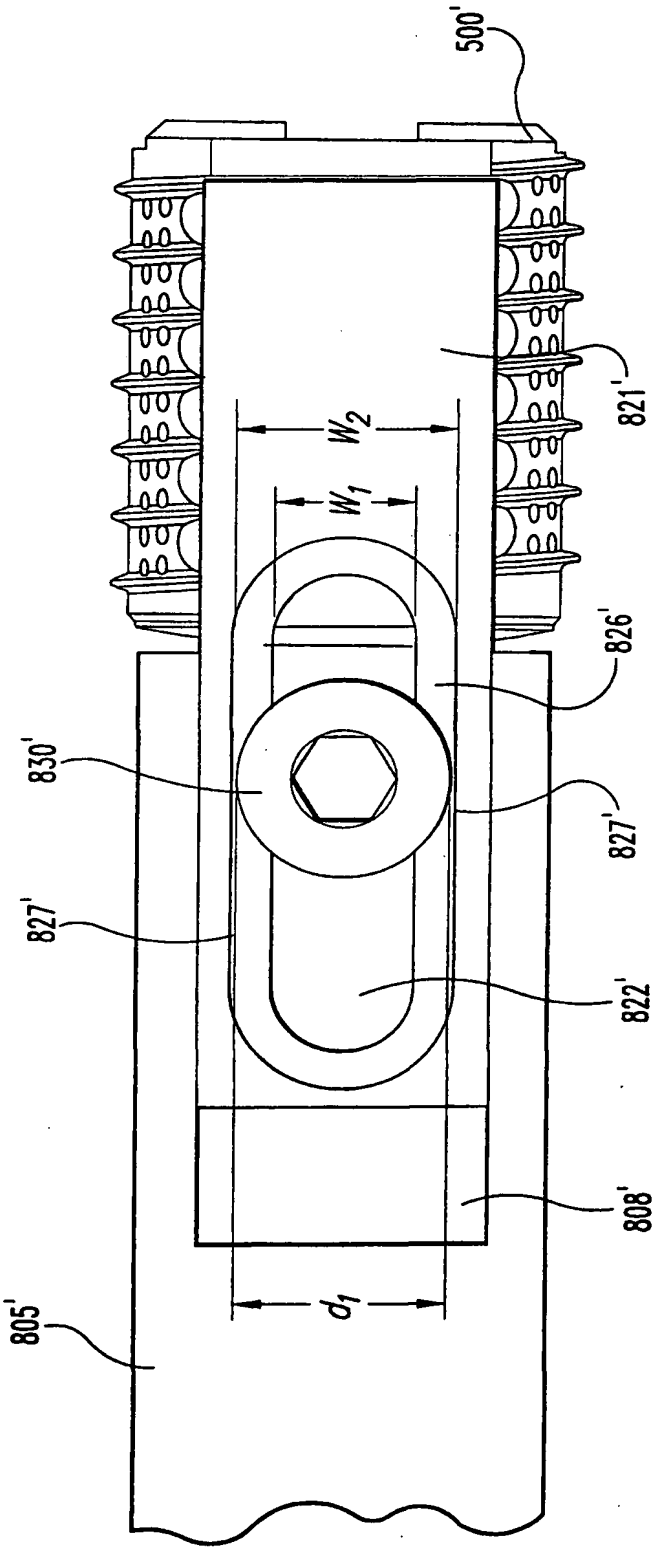


Fig. 14

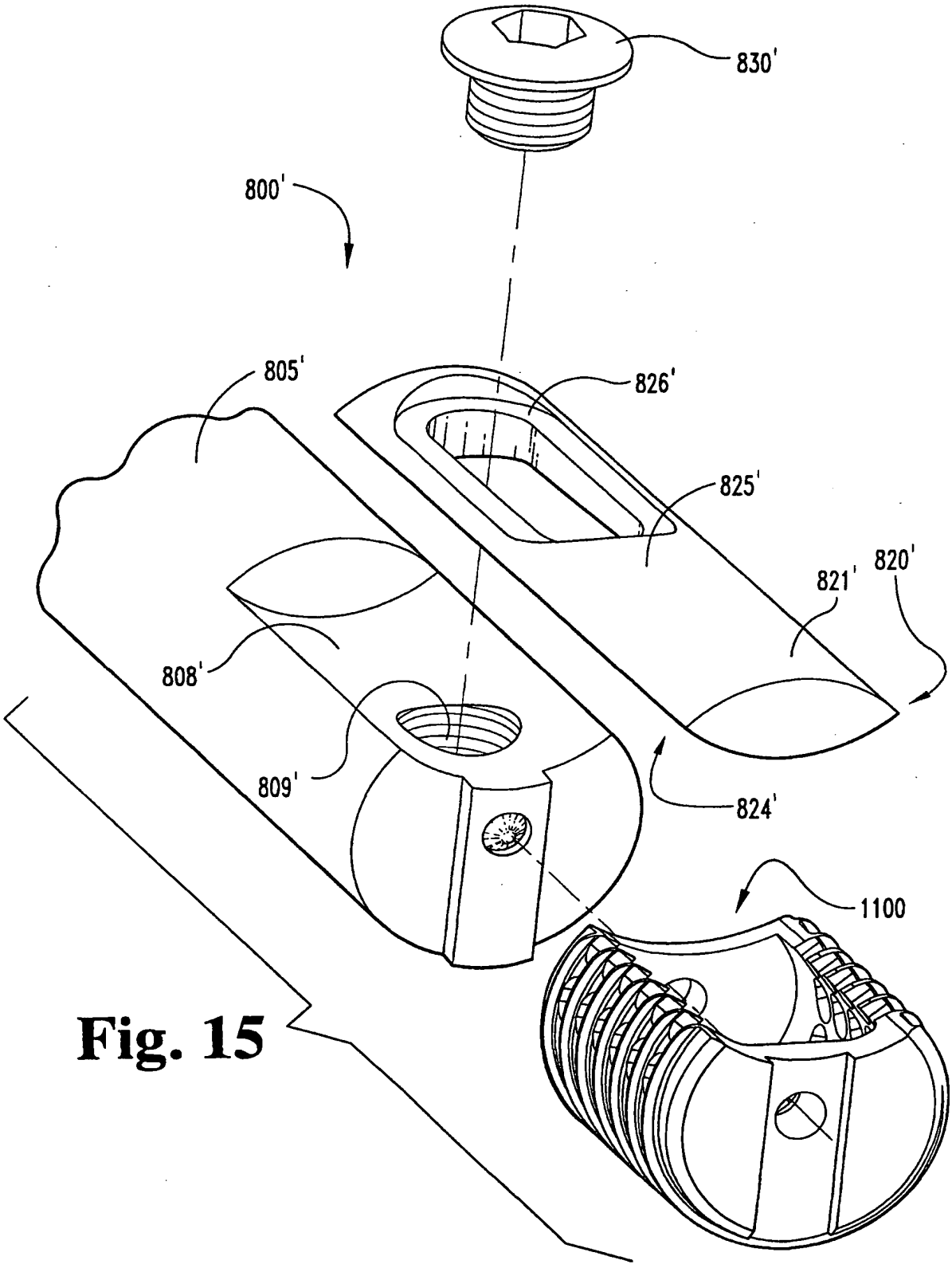


Fig. 15

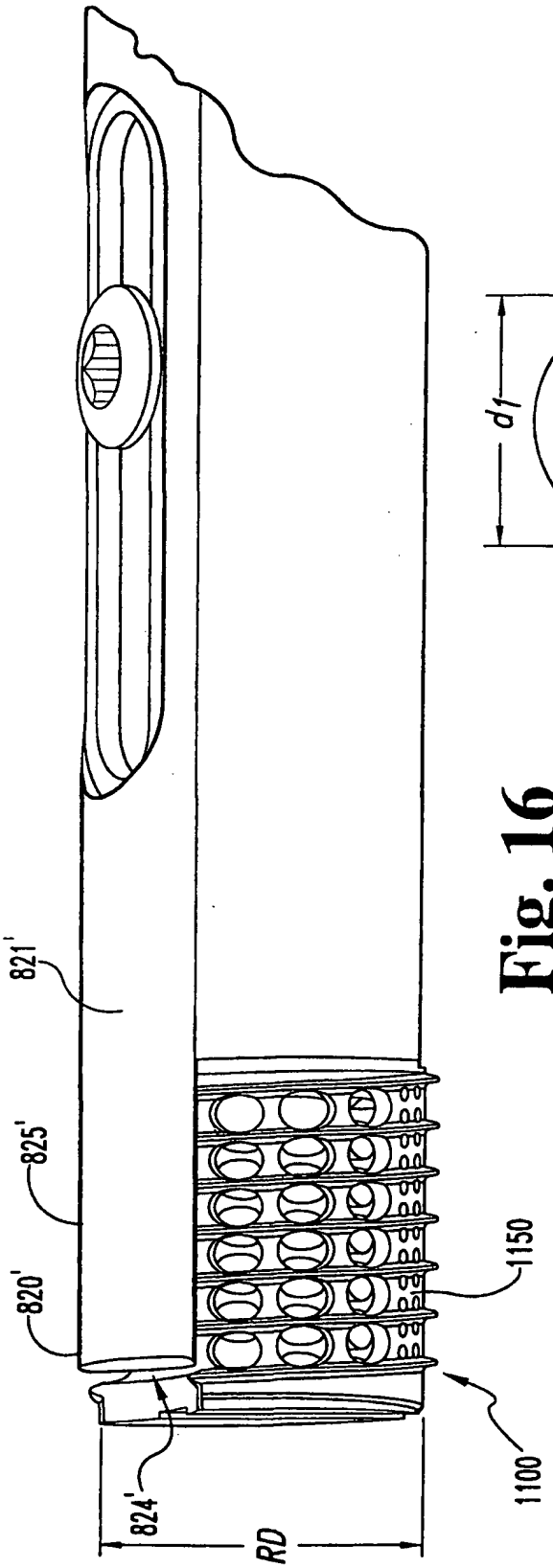


Fig. 16

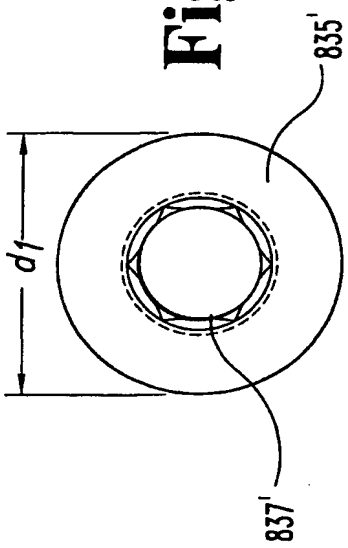


Fig. 18

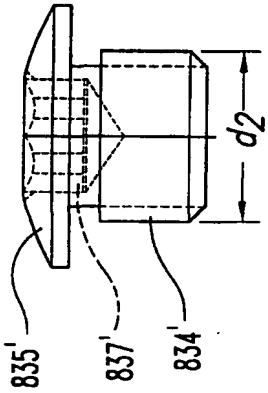


Fig. 19

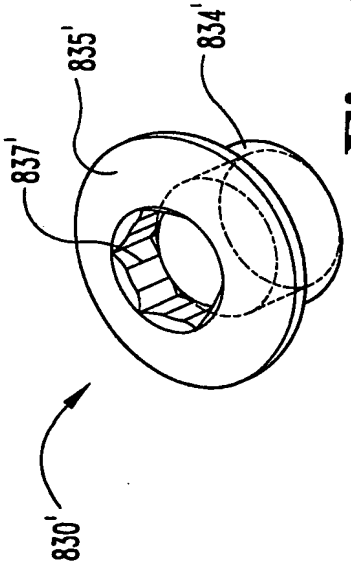


Fig. 17

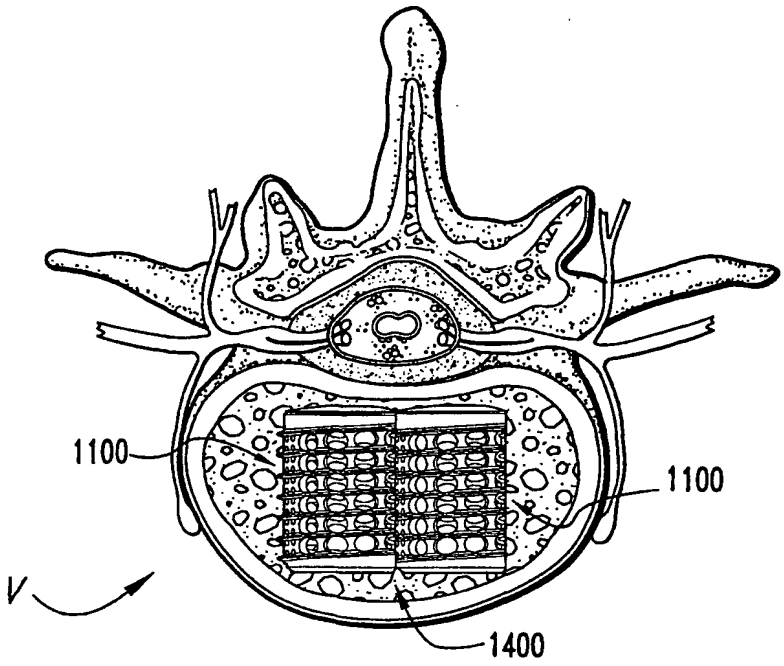


Fig. 20

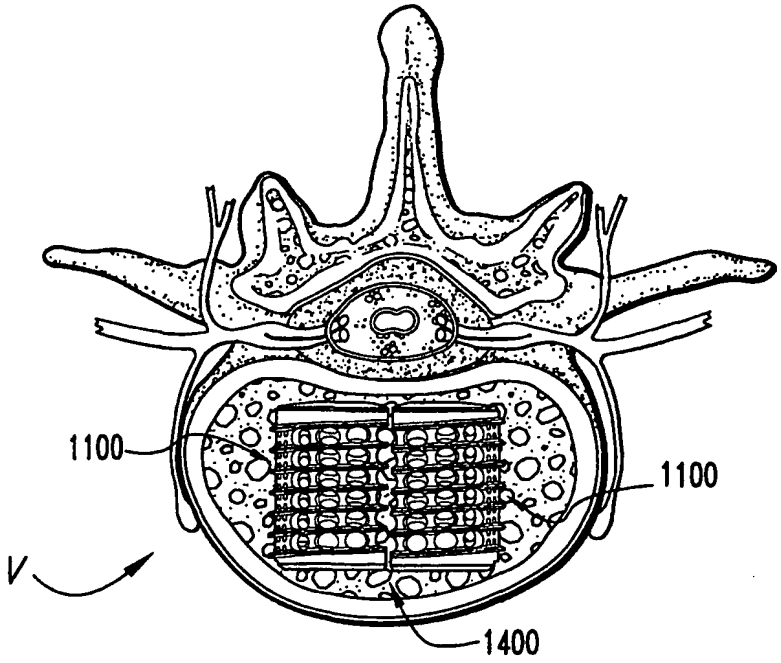


Fig. 21

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

GANDY, K.
WOODARD, EMHARDT, NAUGHTON,
MORIARTY & McNETT
Bank One Center/Tower, suite 3700
111 Monument Circle
INDIANAPOLIS, INDIANA 46204
ETATS-UNIS D'AMERIQUE

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	20.04.2001
Applicant's or agent's file reference 9904PC1/2280	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/00604	11/01/2000	11/01/1999

Applicant
SDGI HOLDINGS, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Terzic, K Tel.+49 89 2399-2052

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
9904PC1/2280		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/00604	11/01/2000	11/01/1999
International Patent Classification (IPC) or national classification and IPC A61F2/44		
Applicant SDGI HOLDINGS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09/08/2000	20.04.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Hedels, B Telephone No. +49 89 2399 2329

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/00604

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-20	as originally filed				

Claims, No.:

1-51,53-57	as originally filed				
52	as received on	06/02/2001	with letter of	05/02/2001	

Drawings, sheets:

1/13-13/13	as originally filed				

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

☐ the description, pages:

☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 40-51.

because:

   ☒ the said international application, or the said claims Nos. 40-51 relate to the following subject matter which does not require an international preliminary examination (*specify*):
   see separate sheet

   ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-39,52-57.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	38,39
	No:	Claims	1,19,20,34,52,53
Inventive step (IS)	Yes:	Claims	38,39
	No:	Claims	2-18,21-33,35-37,54-57
Industrial applicability (IA)	Yes:	Claims	1-39,52-57
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

1. The application comprises 4 independent claims (claims 1,19,52,53) directed to an interbody fusion spacer. The subject-matter of the application is not such as to make it necessary to have more than one independent claim directed to such a spacer. Therefore, in order to comply with Art. 6 PCT (conciseness), one of the above claims should have been selected as the single independent claim directed to a spacer and the remaining claims should have been made appendant thereto.

This objection also applies to the two independent claims 20 and 34 directed to an interbody fusion implant system. These claims should have been replaced by a single claim incorporating a spacer as defined in claim 1.

The claims on file do not meet the requirement of conciseness (Art. 6 PCT).

2. The features of the independent claims 1,19,20,34, 52 and 53 are anticipated by the device and system disclosed in US-A-5 593 409 (D1) (see Figs. 25, 42 and 43 the implants 900a and 900b).
The spacers 900a,b depicted in Fig. 43 are schematic representations. It goes without saying that these spacers have side openings as described in connection with the antecedent embodiments.
Hence, the subject-matter of these claims does not meet the requirement of novelty (Art. 33(2) PCT).

3. The methods defined in claims 40-51 relate to methods for treatment of the human body by surgery or therapy.
The International Preliminary Examining Authority is not required to carry out an international preliminary examination on such claims (Rule 67.1(iv)).

4. In the light of the A-documents cited in the international search report with respect to the independent claim 38 defining a spacer insertion tool, it is considered as obvious that the invention as claimed in claims 38 and 39 meets the criteria mentioned in Art. 33(1) PCT, i.e. it appears to be novel, to involve an inventive step and to be industrially applicable.

The subject-matter of claims 38,39, however, lacks unity to the matter specified in the remaining claims since there are no common "special technical features" in terms of

Rule 13.1 and 13.2 linking these matters.

5. Claim 1 as well as the independent claim 38 have not been worded in the two-part form incorporating in its pre-characterising portion the features disclosed in the closest prior art (Rule 6.3 (b), see the decision of the Board of Appeal T 13/84).

6. The technical problem solved by the characterising features of claim 1 compared to the device of D1 has not been indicated in the response (Rule 5.1 (a) (iii)).

7. Dependent claims can only meet the PCT requirements when related to an independent claim complying with Art. 33(1) PCT.

8. Reference signs are lacking throughout the claims (Rule 6.2 (b)).

9. The description has not been brought into line with the new claims (Rule 5.1 (a) iii)).

10. D1 should have been indicated in the description (Rule 5.1 (a) (ii)).

(b) preparing said adjacent vertebrae to receive the elongated body in an intervertebral space between adjacent vertebrae; and

(c) placing the first elongated body into the intervertebral space.

47. The method of claim 46, further comprising packing osteogenic material into said interior cavity of said first spacer prior to the placing step.

48. The method of claim 46, further comprising implanting a second spacer into the intervertebral space after the placing step.

49. The method of claim 48, further comprising orienting said second spacer so that it nests within said first spacer.

50. The method of claim 49, wherein said first and second interbody fusion spacers are comprised of metal.

51. The method of claim 50, wherein said first elongated body has a first plurality of openings for bone ingrowth extending from said first outer surface into said interior cavity.

52. An interbody fusion spacer, comprising:

an elongate body having end walls and a side wall extending between said end walls, said side wall and said end walls defining an interior cavity, said side walls further defining an opening configured for passage of osteogenic material into said cavity;

said end walls each having an external profile comprising a first portion defining an arc of a circle, said arc extending from 180° to 324° around the circle; said external profile also comprising a second portion defining a concave surface;

P. ENT COOPERATION TREAT

RECEIVED
NOV 14 2000
Woodard, Emhardt, Naughton, Moriarty & McNett

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
GANDY, K.
WOODARD, EMHARDT, NAUGHTON,
MORIARTY & McNETT
Bank One Center/Tower, suite 3700
111 Monument Circle
INDIANAPOLIS, INDIANA 46204
ETATS-UNIS D'AMERIQUE

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	06.11.2000
Applicant's or agent's file reference: 9904PC1/2280	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/00604	11/01/2000	11/01/1999

International Patent Classification (IPC) or both national classification and IPC
A61F2/44

Applicant
SDGI HOLDINGS, INC.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

ENTERED 2-6-01

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain document cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 11/05/2001.

Name and mailing address of the international preliminary examining authority:
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer / Examiner
Hedels, B

Formalities officer (incl. extension of time limits)
Terzic, K
Telephone No. +49 89 2399 2052

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-20 as originally filed

Claims, No.:

1-57 as originally filed

Drawings, sheets:

1/13-13/13 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 40-51,

because:

☒ the said international application, or the said claims Nos. 40-51 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1,19,20,34,52,53
Inventive step (IS)	Claims	
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1. The application comprises 4 independent claims (claims 1,19,52,53) directed to an interbody fusion spacer. The subject-matter of the application is not such as to make it necessary to have more than one independent claim directed to such a spacer. Therefore, in order to comply with Art. 6 PCT (conciseness), one of the above claims should be selected as the single independent claim and the remaining claims be made appendant thereto.

The claims on file do not meet the requirement of conciseness (Art. 6 PCT).

This objection also applies to the two independent claims 20 and 34 directed to an interbody fusion implant system. These claims should be replaced by a single claim incorporating a spacer as defined in claim 1.

2. The features of the independent claims 1,19,20,34, 52 and 53 are anticipated by the device and system disclosed in US-A-5 593 409 (D1) (see Figs. 42 and 43 the implants 900a and 900b).
Hence, the subject-matter of these claims does not meet the requirement of novelty (Art. 33(2) PCT).

3. The methods defined in claims 40-51 relate to methods for treatment of the human body by surgery or therapy.

The International Preliminary Examining Authority is not required to carry out an international preliminary examination on such claims (Rule 67.1(iv)).

Claims 40-51 should therefore be deleted.

4. The applicant is invited to file a fresh set of claims overcoming the above objections.

5. Any new claim 1 directed to a spacer will have to be worded in the two-part form incorporating in its pre-characterising portion the features disclosed in D1 as the closest prior art (Rule 6.3 (b), see the decision of the Board of Appeal T 13/84).

6. In order to be able to assess the question of inventive step, the applicant is asked

to indicate in the response which technical problem is solved by the characterising features of the new claim 1 compared to the device of D1 (Rule 5.1 (a) (iii)).

7. Reference signs will have to be used throughout the claims (Rule 6.2 (b)).

8. The description will have to be brought into line with the new claims (Rule 5.1 (a) iii)).

9. D1 should be indicated in the description (Rule 5.1 (a) (ii)).

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

GANDY, Kenneth, A.
Woodard, Emhardt, Naughton,
Moriarty & McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204
ETATS-UNIS D'AMERIQUE

RECEIVED
APR 11 2001
Woodard, Emhardt, Naughton, Moriarty & McNett

Date of mailing (day/month/year) 28 March 2001 (28.03.01)	
Applicant's or agent's file reference 9904PC1/2280	**IMPORTANT NOTIFICATION**
International application No. PCT/US00/00604	**International filing date** (day/month/year) 11 January 2000 (11.01.00)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [ ] the agent [ ] the common representative

Name and Address	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [ ] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address	State of Nationality	State of Residence
ESTES, Bradley, T. 5169 Tarrytown Drive Memphis, TN 38117 United States of America	US	US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:
Additional applicant/inventor for US only.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Marie-José Devillard
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

003925791

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

GANDY, Kenneth, A.
Woodard, Emhardt, Naughton,
Moriarty & McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 28 March 2001 (28.03.01)	
Applicant's or agent's file reference 9904PC1/2280	**IMPORTANT NOTIFICATION**
International application No. PCT/US00/00604	**International filing date** (day/month/year) 11 January 2000 (11.01.00)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [ ] the agent [ ] the common representative

Name and Address	State of Nationality	State of Residence
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[X] the person [ ] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address	State of Nationality	State of Residence
RAY, III, Eddie, F. 1781 Fernhall Cove Collierville, TN 38017 United States of America	US	US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:
Additional applicant/inventor for US only.

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Marie-José Devillard
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

4002-2280

RECEIVED

OCT 10 2000

Woodard, Emhardt, Naughton, Moriarty & McNett

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

To:
WOODARD, EMHARDT, NAUGHTON,
MORIARTY & McNETT
Attn. GANDY, K.
Bank One Center/Tower, suite 3700
111 Monument Circle
INDIANAPOLIS, INDIANA 46204
UNITED STATES OF AMERICA

Applicant's or agent's file reference 9904PC1/2280	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 00/00604	International filing date *(day/month/year)* 11/01/2000
Applicant SDGI HOLDINGS, INC.	

Date of mailing *(day/month/year)* 03/10/2000

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

ENTERED
12-3-00

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Nathalie Geisler

Form PCT/ISA/220 (July 1998)

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

GANDY, Kenneth, A.
Woodard, Emhardt, Naughton,
Moriarty & McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 14 April 2000 (14.04.00)	
Applicant's or agent's file reference 9904PC1/2280	**IMPORTANT NOTIFICATION**
International application No. PCT/US00/00604	International filing date (day/month/year) 11 January 2000 (11.01.00)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 11 January 1999 (11.01.99)
Applicant SDGI HOLDINGS, INC. et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An **asterisk(*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. The **letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
11 Janu 1999 (11.01.99)	60/115,388	US	11 Apri 2000 (11.04.00)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Taïeb Akremi

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

To:

GANDY, Kenneth, A.
Woodard, Emhardt, Naughton,
Moriarty & McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204
ETATS-UNIS D'AMERIQUE

INFORMATION CONCERNING ELECTED OFFICES NOTIFIED OF THEIR ELECTION

(PCT Rule 61.3)

Date of mailing (day/month/year) 06 October 2000 (06.10.00)	
Applicant's or agent's file reference 9904PC1/2280	**IMPORTANT INFORMATION**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/US00/00604	11 January 2000 (11.01.00)	11 January 1999 (11.01.99)

Applicant
SDGI HOLDINGS, INC. et al

1. The applicant is hereby informed that the International Bureau has, according to Article 31(7), notified each of the following Offices of its election:

   AP :GH,GM,KE,LS,MW,SD,SL,SZ,TZ,UG,ZW
   EP :AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE
   National :AU,BG,CA,CN,CZ,DE,IL,JP,KP,KR,MN,NO,NZ,PL,RO,RU,SE,SK,US

2. The following Offices have waived the requirement for the notification of their election; the notification will be sent to them by the International Bureau only upon their request:

   EA :AM,AZ,BY,KG,KZ,MD,RU,TJ,TM
   OA :BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG
   National :AE,AL,AM,AT,AZ,BA,BB,BR,BY,CH,CR,CU,DK,DM,EE,ES,FI,GB,GD,GE,GH, GM,HR,HU,ID,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MW,MX,PT,SD, SG,SI,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

3. The applicant is reminded that he must enter the "national phase" **before the expiration of 30 months from the priority date** before each of the Offices listed above. This must be done by paying the national fee(s) and furnishing , if prescribed, a translation of the international application (Article 39(1)(a)), as well as, where applicable, by furnishing a translation of any annexes of the international preliminary examination report (Article 36(3)(b) and Rule 74.1).

   Some offices have fixed time limits expiring later than the above-mentioned time limit. For detailed information about the applicable time limits and the acts to be performed upon entry into the national phase before a particular Office, see Volume II of the PCT Applicant's Guide.

   The entry into the European regional phase is postponed **until 31 months from the priority date** for all States designated for the purposes of obtaining a European patent.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer:
F. Baechler

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

RECEIVED

SEP 29 2000

Woodard, Emhardt, Moriarty &

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:
GANDY, K.
WOODARD, EMHARDT, NAUGHTON,
MORIARTY & McNETT
Bank One Center/Tower, suite 3700
111 Monument Circle
INDIANAPOLIS, INDIANA 46204
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rules 59.3(e) and 61.1(b), first sentence and Administrative Instructions, Section 601(a))

Date of mailing *(day/month/year)*	22.09.00
Applicant's or agent's file reference: 9904PC1/2280	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 00/00604	11/01/2000	11/01/1999

Applicant: SDGI HOLDINGS, INC.

1. The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

09/08/2000

2. This date of receipt is:

- [X] the actual date of receipt of the demand by this Authority (Rule 61.1(b)).
- [ ] the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).
- [ ] the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. [ ] **ATTENTION:** That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide*, Volume II.

[ ] *(If applicable)* This notification confirms the information given by telephone, facsimile transmission or in person on: _____

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	KEMLE S Y G Tel. (+49-89) 2399-8588

EUROPÄISCHES PATENTAMT · EUROPEAN PATENT OFFICE · OFFICE EUROPÉEN DES BREVETS

PCT INTERNATIONAL APPLICATION TRANSMITTAL LETTER	DATE 11 January 2000
REGARDING THE INTERNATIONAL APPLICATION OF SDGI HOLDINGS, INC., etal.	DOCKET OR REFERENCE NUMBER 9904PC1/2280

ENTITLED
INTERVERTEBRAL SPACERS WITH SIDE WALL ACCESSIBLE INTERIOR CAVITY

Certification under 37 CFR 1.10 (if applicable)

EL016470231US
"Express Mail" mailing number

11 January 2000
Date of Deposit

I hereby certify that this application is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Linda S.W. Conrad
(Typed or printed name of person mailing application)

Linda S.W. Conrad
(Signature of person mailing application)

To the United States Receiving Office (RO/US):

Accompanying this transmittal letter is the above-identified International application, including a completed Request form (PCT/RO/101). Please process the application according to the provisions of the Patent Cooperation Treaty.

The following requests are made of the RO/US:

1. [XX] PREPARATION AND TRANSMITTAL OF CERTIFIED COPY OF PRIORITY DOCUMENTS—Please prepare and transmit to the International Bureau a certified copy of the United States origin priority documents identified in Box VI of the Request form (37 CFR 1.451).

   To cover the cost of copy preparation and certification (37 CFR 1.19(a)(3) and (b)(1)),
   [XX] a (check) (money order) in the amount of $ 15.00 included in fee is attached to this transmittal letter.
   [ ] the RO/US is hereby authorized to charge the following deposit account no.: _____.

2. [XX] CHOICE OF INTERNATIONAL SEARCHING AUTHORITY—It is requested that the International Search be performed by the following International Searching Authority:

   [ ] United States Patent and Trademark Office (ISA/US)
   [XX] European Patent Office (ISA/EP)

   The appropriate Search fee for the above-named Authority is indicated on the Fee Calculation Sheet (PCT/RO/101 Annex).

3. [ ] SUPPLEMENTAL SEARCH FEES (ONLY WHEN ISA/US CONDUCTS THE INTERNATIONAL SEARCH.)—Please charge any Supplemental Search fees that may be required by the United States International Searching Authority (ISA/US) to deposit account no.: _____.

   I understand that the authorization to charge deposit account for additional compensation is not in each instance and that it in no way limits my right to submit a protest against the charging of the Search Additional Search Fees, but is merely an administrative aid to assure that the ISA/US may timely complete the Search Report.

NOTE: SUPPLEMENTAL SEARCH FEES FOR ISA/EP ARE PAYABLE DIRECTLY TO THE EUROPEAN PATENT OFFICE

4. [XX] DISCLOSURE INFORMATION—In order to assist in screening the accompanying International application for purposes of determining whether a license for foreign transmittal should and could be granted and for other purposes, the following information is supplied:

   A. [ ] There is no prior filed application relating to this invention.

   B. [XX] There is a prior application, serial number 60/115,388 filed on 11 January 1999 (11.01.99) which contains subject matter that is

      1. [ ] substantially identical to that of the accompanying International application.
      2. [ ] less than that of the accompanying International application. The additional subject matter of the International application appears on pages(s) and line(s) _____.
      3. [X] more than that of the accompanying International application.

   C. [ ] Disclosure information cannot be covered by the language of Points 4A or 4B above due to the involvement of several prior applications or for other reasons. A separate sheet on which the disclosure information is explained is attached to this transmittal letter.

5. [XX] REQUEST FOR FOREIGN TRANSMITTAL LICENSE—According to the provisions of 35 U.S.C. 184 and 37 CFR 5.11, a license to transmit the accompanying International application to foreign agencies or international authorities is hereby requested.

SIGNER IS THE	NAME OF SIGNER (typed)
[ ] APPLICANT [ ] COMMON REPRESENTATIVE [X] ATTORNEY/AGENT REG. NO. #33,386	Kenneth A. GANDY SIGNATURE Kenneth A Gandy

This sheet is not part of and does not count as a sheet of the international application.

PCT

FEE CALCULATION SHEET
Annex to the Request

For receiving Office use only

International application No.

Date stamp of the receiving Office

Applicant's or agent's file reference: 9904PC1/2280

Applicant: SDGI HOLDINGS, INC., etal.

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE . . . . . 240 T

2. SEARCH FEE . . . . . 1005 S

International search to be carried out by EP

(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application contains 49 sheets.

first 30 sheets 427 b1

19 remaining sheets x 10 additional amount = 190 b2

Add amounts entered at b1 and b2 and enter total at B . . . . 617 B

Designation Fees

The international application contains 83 designations.

8 number of designation fees payable *(maximum 10)* x ~~88~~ 92 amount of designation fee = MAX. 736 D

Add amounts entered at B and D and enter total at I . . . . . 1353 I

(Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT *(if applicable)* . . . . . 15 P

5. TOTAL FEES PAYABLE . . . . . $2613.00 TOTAL

Add amounts entered at T, S, I and P, and enter total in the TOTAL box

☐ The designation fees are not paid at this time.

MODE OF PAYMENT

☒ authorization to charge deposit account (see below)	☐ bank draft	☐ coupons
☒ cheque	☐ cash	☐ other *(specify)*:
☐ postal money order	☐ revenue stamps	

DEPOSIT ACCOUNT AUTHORIZATION *(this mode of payment may not be available at all receiving Offices)*

The RO/ US

☐ is hereby authorized to charge the total fees indicated above to my deposit account.

☒ *(this check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit)* is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

☐ is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account.

23-3030 Deposit Account No.

11 January 2000 Date *(day/month/year)*

Signature Kenneth A. Gandy, #33,386

See Notes to the fee calculation sheet

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 9904PC1/2280

Box No. I TITLE OF INVENTION

INTERVERTEBRAL SPACERS WITH SIDE WALL ACCESSIBLE INTERIOR CAVITY

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

SDGI HOLDINGS, INC.
300 Delaware Avenue, Suite 508
Wilmington, Delaware 19801 US

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BOYD, Lawrence M.
688 S. McLean Boulevard
Memphis, Tennessee 38104 US

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

GANDY, Kenneth A.
WOODARD, EMHARDT, NAUGHTON, MORIARTY & MCNETT
Bank One Center/Tower, Suite 3700
111 Monument Circle
Indianapolis, Indiana 46204 US
SEE CONTINUATION TO BOX NO. IV ON SHEET NO. 4

Telephone No. 317-634-3456

Facsimile No. 317-637-7561

Teleprinter No.

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BURKUS, J. Kenneth
7162 Williams Hill Road
Columbus, Georgia 31904 US

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

DORCHAK, John D.
P.O. Box 400
Midland, Georgia 31820 US

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

- [ ] Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes; at least one must be marked)*:

Regional Patent

☒ AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT

☒ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒ AE United Arab Emirates
☒ AL Albania
☒ AM Armenia
☒ AT Austria
☒ AU Australia
☒ AZ Azerbaijan
☒ BA Bosnia and Herzegovina
☒ BB Barbados
☒ BG Bulgaria
☒ BR Brazil
☒ BY Belarus
☒ CA Canada
☒ CH and LI Switzerland and Liechtenstein
☒ CN China
☒ CR Costa Rica
☒ CU Cuba
☒ CZ Czech Republic
☒ DE Germany
☒ DK Denmark
☒ DM Dominica
☒ EE Estonia
☒ ES Spain
☒ FI Finland
☒ GB United Kingdom
☒ GD Grenada
☒ GE Georgia
☒ GH Ghana
☒ GM Gambia
☒ HR Croatia
☒ HU Hungary
☒ ID Indonesia
☒ IL Israel
☒ IN India
☒ IS Iceland
☒ JP Japan
☒ KE Kenya
☒ KG Kyrgyzstan
☒ KP Democratic People's Republic of Korea
☒ KR Republic of Korea
☒ KZ Kazakhstan
☒ LC Saint Lucia
☒ LK Sri Lanka
☒ LR Liberia
☒ LS Lesotho
☒ LT Lithuania
☒ LU Luxembourg
☒ LV Latvia
☒ MA Morocco
☒ MD Republic of Moldova
☒ MG Madagascar
☒ MK The former Yugoslav Republic of Macedonia
☒ MN Mongolia
☒ MW Malawi
☒ MX Mexico
☒ NO Norway
☒ NZ New Zealand
☒ PL Poland
☒ PT Portugal
☒ RO Romania
☒ RU Russian Federation
☒ SD Sudan
☒ SE Sweden
☒ SG Singapore
☒ SI Slovenia
☒ SK Slovakia
☒ SL Sierra Leone
☒ TJ Tajikistan
☒ TM Turkmenistan
☒ TR Turkey
☒ TT Trinidad and Tobago
☒ TZ United Republic of Tanzania
☒ UA Ukraine
☒ UG Uganda
☒ US United States of America
☒ UZ Uzbekistan
☒ VN Viet Nam
☒ YU Yugoslavia
☒ ZA South Africa
☒ ZW Zimbabwe

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

☐ .....
☐ .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Supplemental Box *If the Supplemental Box is not used, this sheet should not be included in the request.*

1. If, in any of the Boxes, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:

(i) if more than two persons are involved as applicants and/or inventors and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;

(ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;

(iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;

(iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;

(v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," or "certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "continuation" or "continuation-in-part": in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;

(vi) if, in Box No. VI, there are more than three earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI;

(vii) if, in Box No. VI, the earlier application is an ARIPO application: in such case, write "Continuation of Box No. VI", specify the number of the item corresponding to that earlier application and indicate at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed.

2. If, with regard to the precautionary designation statement contained in Box No. V, the applicant wishes to exclude any State(s) from the scope of that statement: in such case, write "Designation(s) excluded from precautionary designation statement" and indicate the name or two-letter code of each State so excluded.

3. If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerning non-prejudicial disclosures or exceptions to lack of novelty: in such case, write "Statement concerning non-prejudicial disclosures or exceptions to lack of novelty" and furnish that statement below.

Continuation to Box No. IV Agent

WOODARD, Harold R.; EMHARDT, C. David; NAUGHTON, Joseph A., Jr.; MORIARTY, John V.; McNETT, John C.; HENRY, Thomas Q.; DURLACHER, James M.; REEVES, Charles R.; WAGNER, Vincent O.; ZLATOS, Steve; BEREVESKOS, Spiro; BAHRET, William F.; BROWNING, Clifford W.; FRISK, R. Randall; LUEDERS, Daniel J.; GANDY, Kenneth A.; THOMAS, Timothy N.; SISSELMAN, Kerry P.; JONES, Kurt N.; ALLIE, John H.; BANTA, Holiday W.; COLE, Troy J.; PAYNTER, L. Scott; LOWES, J. Andrew; MEYER, Charles J.; HARRIS, Darrin Wesley; SCHANTZ, Matthew R.; COY, Gregory B.; HIDAY, Lisa A.; DANILUCK, John V.; BROWN, Christopher A.; SCHWARTZ, Jason J.; USHER, Arthur J. IV; COLLIER, Douglas A.; MYERS, James B. Jr.; STEVENS, Scott J., and ROWE, James L., all of Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, Indiana 46204 United States of America

Box No. VI PRIORITY CLAIM ☐ Further priority claims are indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) (01.11.99) 11 January 1999	60/115,388	US		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s): (1)

** Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)* : ISA/ EP

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date (day/month/year)	Number	Country (or regional Office)
11 January 1999	60/115,388	US

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	:	5
description (excluding sequence listing part)	:	20
claims	:	10
abstract	:	1
drawings	:	13
sequence listing part of description	:	n/a
Total number of sheets	:	49

This international application is **accompanied** by the item(s) marked below:

1. ☒ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☒ other *(specify)*: Transmittal Letter (dup)

Figure of the drawings which should accompany the abstract: 1

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Applicant(s):
SDGI HOLDINGS, INC.
BOYD, Lawrence M.
BURKUS, J. Kenneth
DORCHAK, John D.

Agent:

(Kenneth A. GANDY)

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority (if two or more are competent): ISA/
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
9904PC1/2280		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 00/00604	11/01/2000	11/01/1999
Applicant		
SDGI HOLDINGS, INC.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [X] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/00604

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 40-51
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-37,52-57

An interbody fusion spacer.

2. Claims: 38-39

A spacer insertion tool.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-37,52-57

   An interbody fusion spacer.

2. Claims: 38-39

   A spacer insertion tool.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/00604

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 40-51
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
T/US 00/00604

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 593 409 A (MICHELSON GARY K) 14 January 1997 (1997-01-14) figures 41-43,25,30 column 12, line 55 -column 13, line 22 column 15, line 12 - line 29 claims 1-18	1,3-20, 22-37, 52-57
Y	---	2,21
Y	US 5 645 598 A (BROSNAHAN III ROBERT E) 8 July 1997 (1997-07-08) figures 4,14 column 3, line 39 -column 5, line 61	2,21

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 September 2000	03. 10. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

4

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/00604

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 17209 A (HOECK JAMES E VAN ;SDGI HOLDINGS INC (US); BOYD LAWRENCE M (US); M) 30 April 1998 (1998-04-30) figures 3-8,47-49 page 14, line 11 -page 16, line 4 page 28, line 24 -page 29, line 26	1-37, 52-57
A	EP 0 302 719 A (SHOWELL A W SUGICRAFT LTD) 8 February 1989 (1989-02-08) column 2, line 19 - line 52 figures 1-6	1,19,20, 34,52,53
A	US 4 736 738 A (GLOBEVNIK JOZE ET AL) 12 April 1988 (1988-04-12) figures 12-29 column 4, line 8 - line 36	38,39
A	US 5 423 825 A (LEVINE ANDREW S) 13 June 1995 (1995-06-13) figures 1-17 column 6, line 47 -column 8, line 50	38,39

4

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/00604

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5593409 A	14-01-1997	US 5741253 A	21-04-1998
		US 5015247 A	14-05-1991
		AU 716409 B	24-02-2000
		AU 4445196 A	29-08-1996
		CA 2168835 A	30-04-1994
		CN 1134810 A	06-11-1996
		EP 0732093 A	18-09-1996
		JP 8266563 A	15-10-1996
		TR 960846 A	21-10-1996
		US 5785710 A	28-07-1998
		US 6080155 A	27-06-2000
		US 5505732 A	09-04-1996
		US 5797909 A	25-08-1998
		US 6096038 A	01-08-2000
		US 5484437 A	16-01-1996
		US 5772661 A	30-06-1998
		AT 169811 T	15-09-1998
		AU 3838789 A	12-01-1990
		CA 1332999 A	15-11-1994
		DE 68928790 D	24-09-1998
		DE 68928790 T	25-03-1999
		EP 0419564 A	03-04-1991
		EP 0712607 A	22-05-1996
		WO 8912431 A	28-12-1989
US 5645598 A	08-07-1997	US 5766253 A	16-06-1998
		AU 1748297 A	11-08-1997
		WO 9725946 A	24-07-1997
		US 6102948 A	15-08-2000
WO 9817209 A	30-04-1998	AU 4994697 A	15-05-1998
		EP 0955961 A	17-11-1999
		JP 2000507484 T	20-06-2000
		US 5989289 A	23-11-1999
		US 5888222 A	30-03-1999
EP 0302719 A	08-02-1989	AT 67395 T	15-10-1991
		DE 3864946 A	24-10-1991
		GB 2207607 A,B	08-02-1989
		GR 3002859 T	25-01-1993
		JP 1303148 A	07-12-1989
		JP 2114682 C	06-12-1996
		JP 8022294 B	06-03-1996
		US 4904261 A	27-02-1990
US 4736738 A	12-04-1988	NONE	
US 5423825 A	13-06-1995	AU 4597793 A	04-01-1994
		WO 9325150 A	23-12-1993